IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

WENDY B. DOLIN Individually and as Independent Executor of the Estate of STEWART DOLIN, deceased,	No. 12 CV 6403
Plaintiff,	
vs.	Chicago, Illinois
SMITHKLINE BEECHAM CORPORATION D/B/A GLAXOSMITHKLINE, a Pennsylvania Corporation,	April 4, 2017
Defendant.	9:20 o'clock a.m.

VOLUME 13 A
TRANSCRIPT OF PROCEEDINGS
BEFORE THE HONORABLE WILLIAM T. HART

For the Plaintiff:

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Court reporter:

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Appearances (continued:)

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(312) 876-8000

(The following proceedings were had out of the presence of the jury in open court:)

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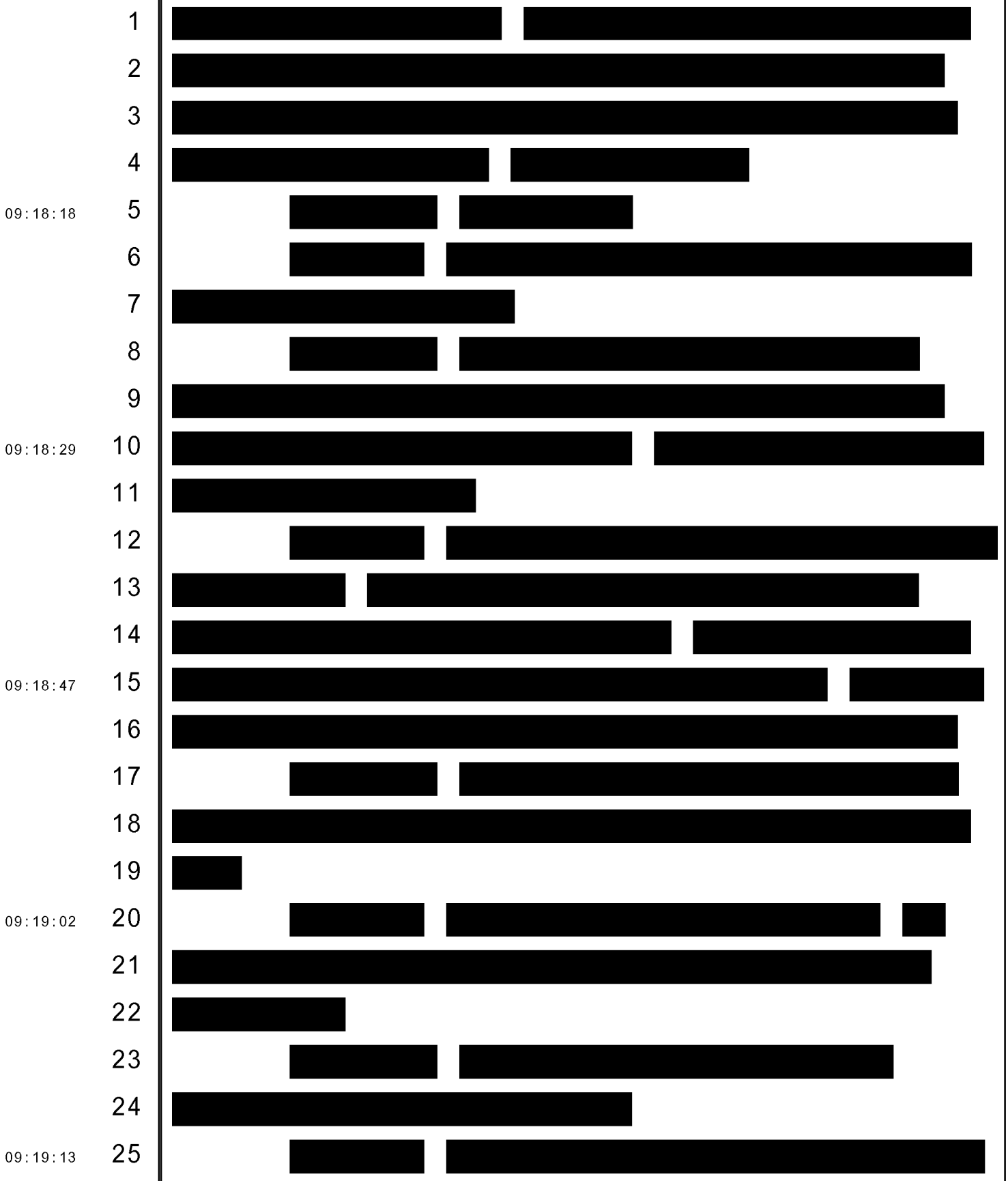
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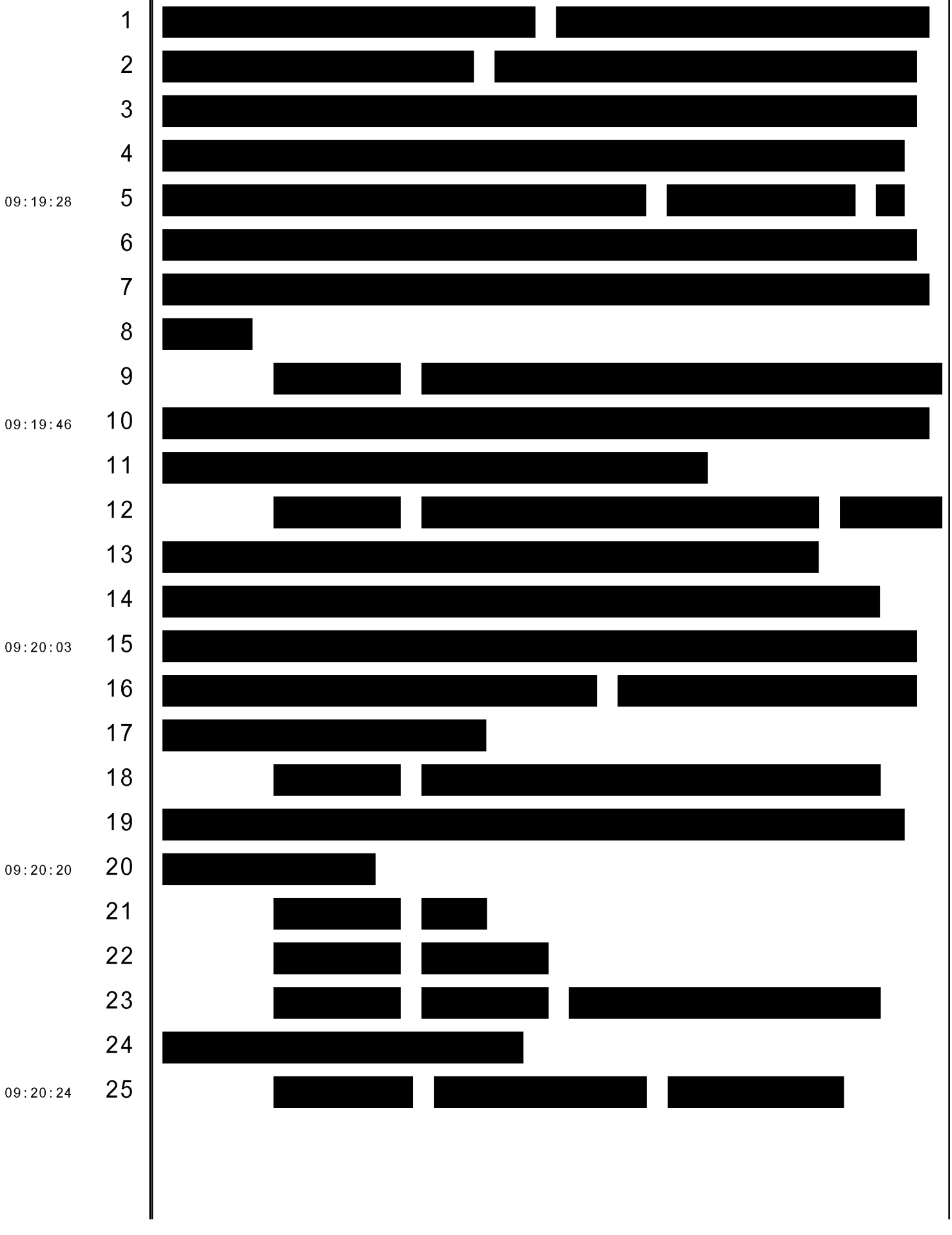
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(The following proceedings were had out of the presence of the jury in open court:)

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(The following proceedings were had in the presence of the jury in open court:)

THE COURT: All right. Thank you very much, ladies and gentlemen. Please be seated.

We'll resume.

MS. HENNINGER: Thank you.

THE COURT: You may proceed, ma'am.

MS. HENNINGER: Thank you.

If it please the Court, counsel. Good morning, ladies and gentlemen.

WENDY DOLIN, PLAINTIFF'S WITNESS, PREVIOUSLY SWORN

CROSS EXAMINATION

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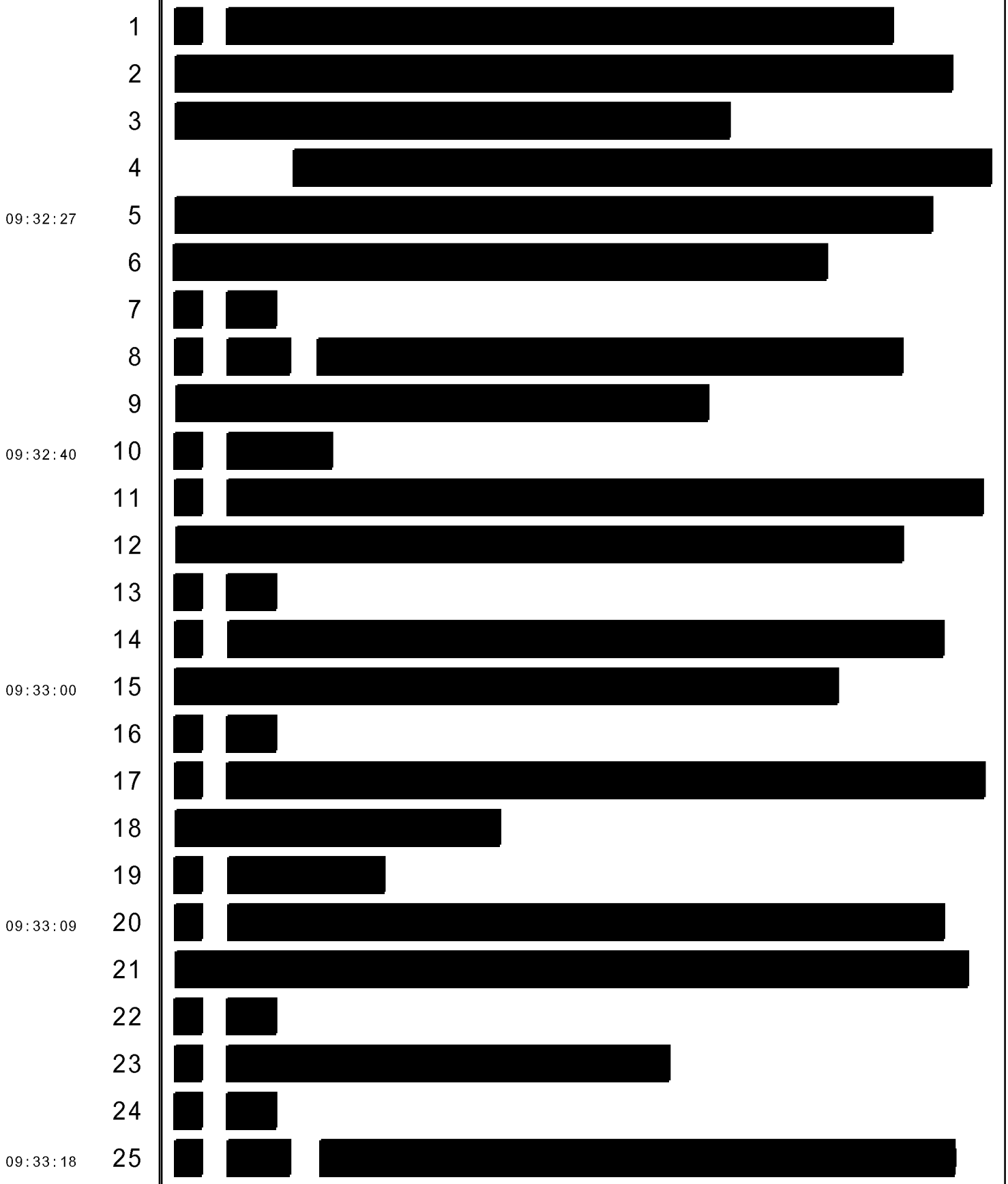
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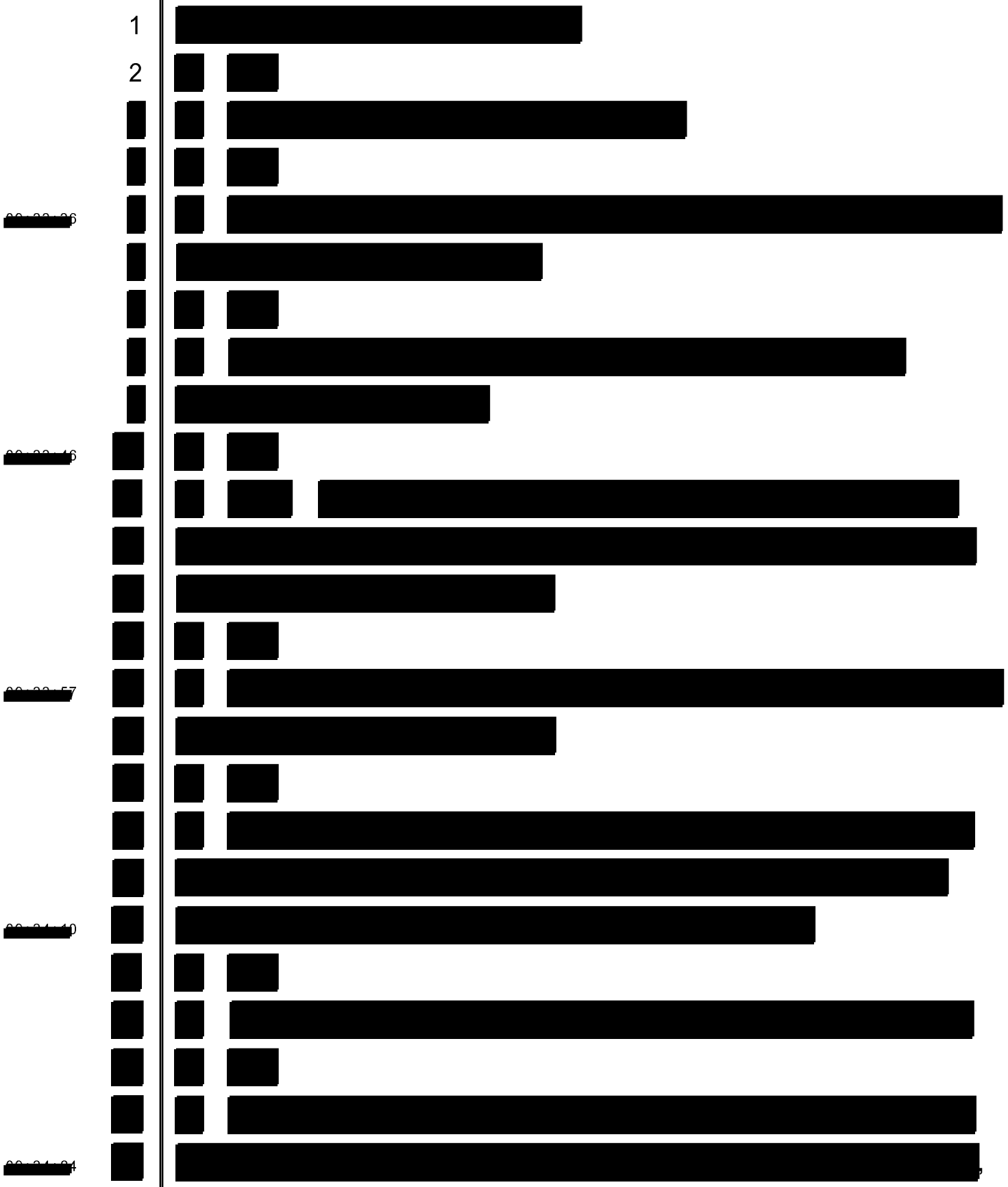

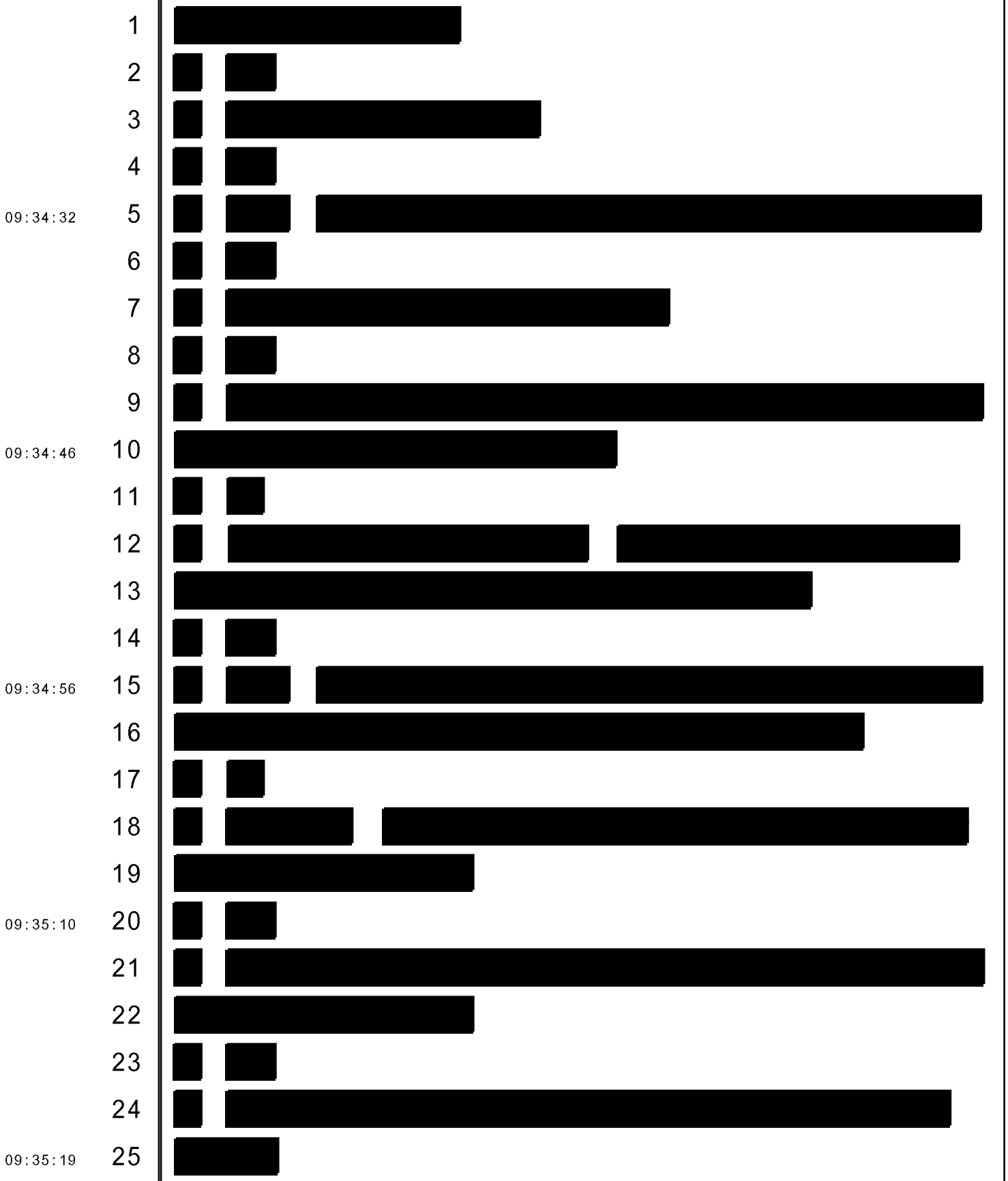
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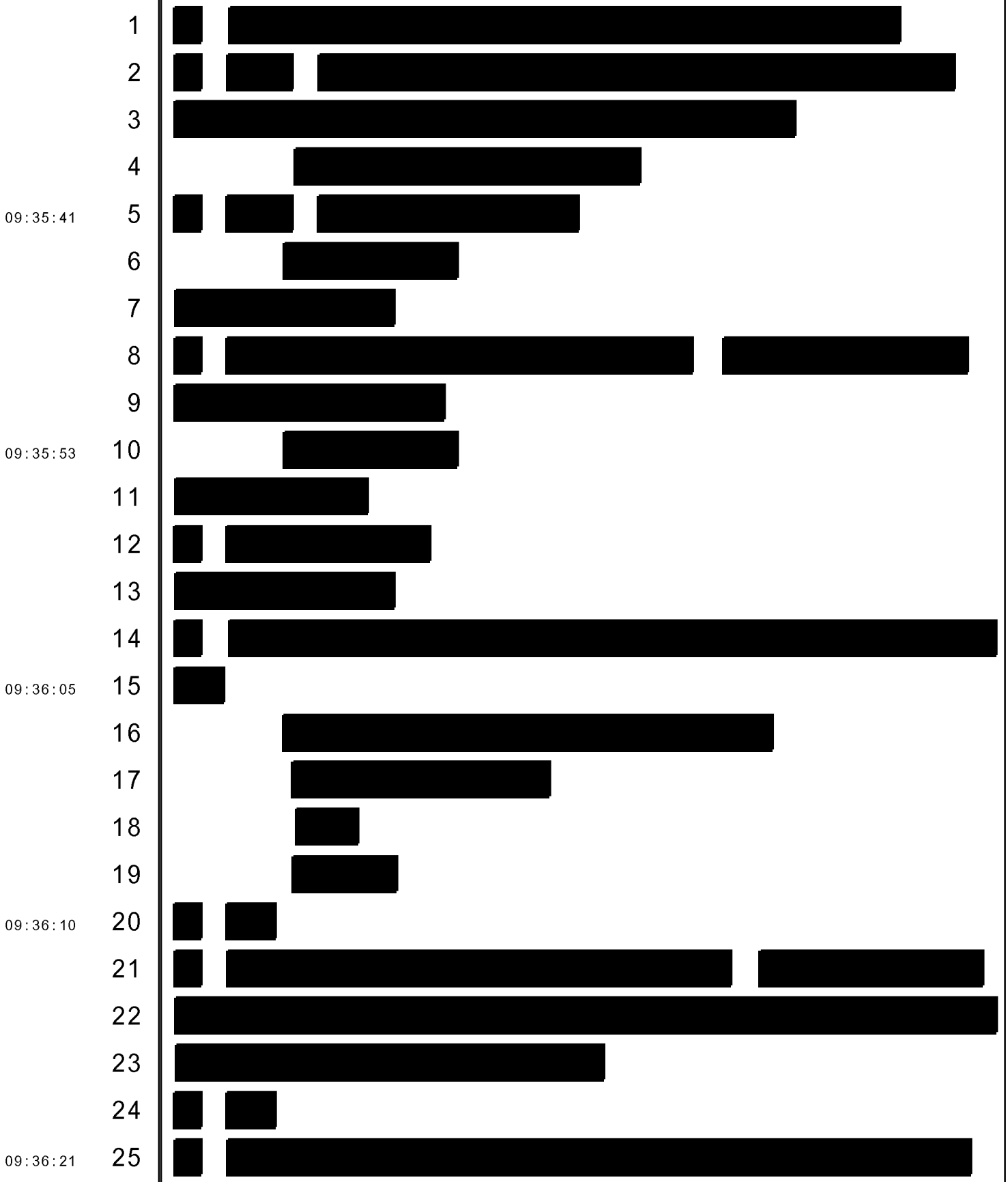
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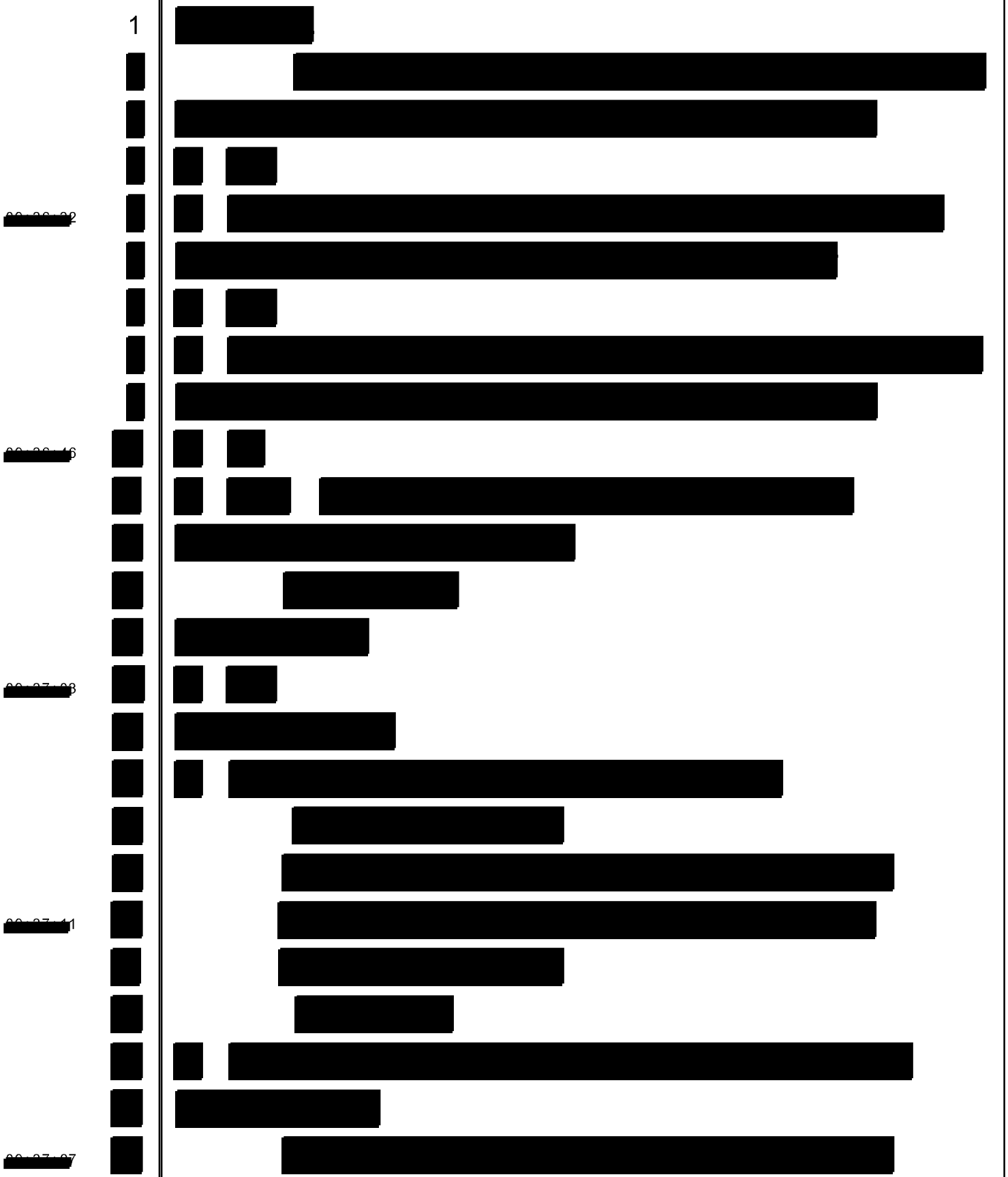

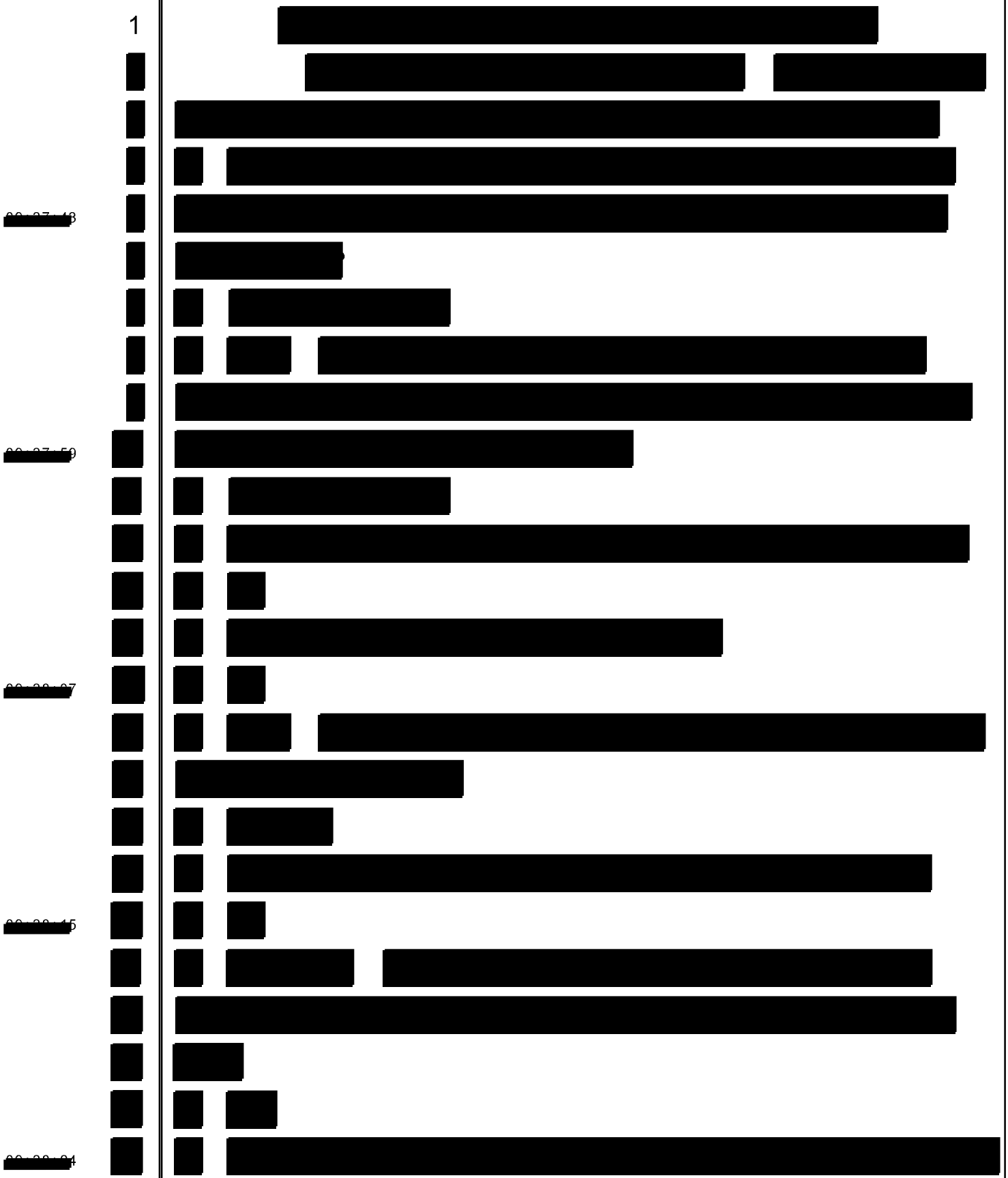


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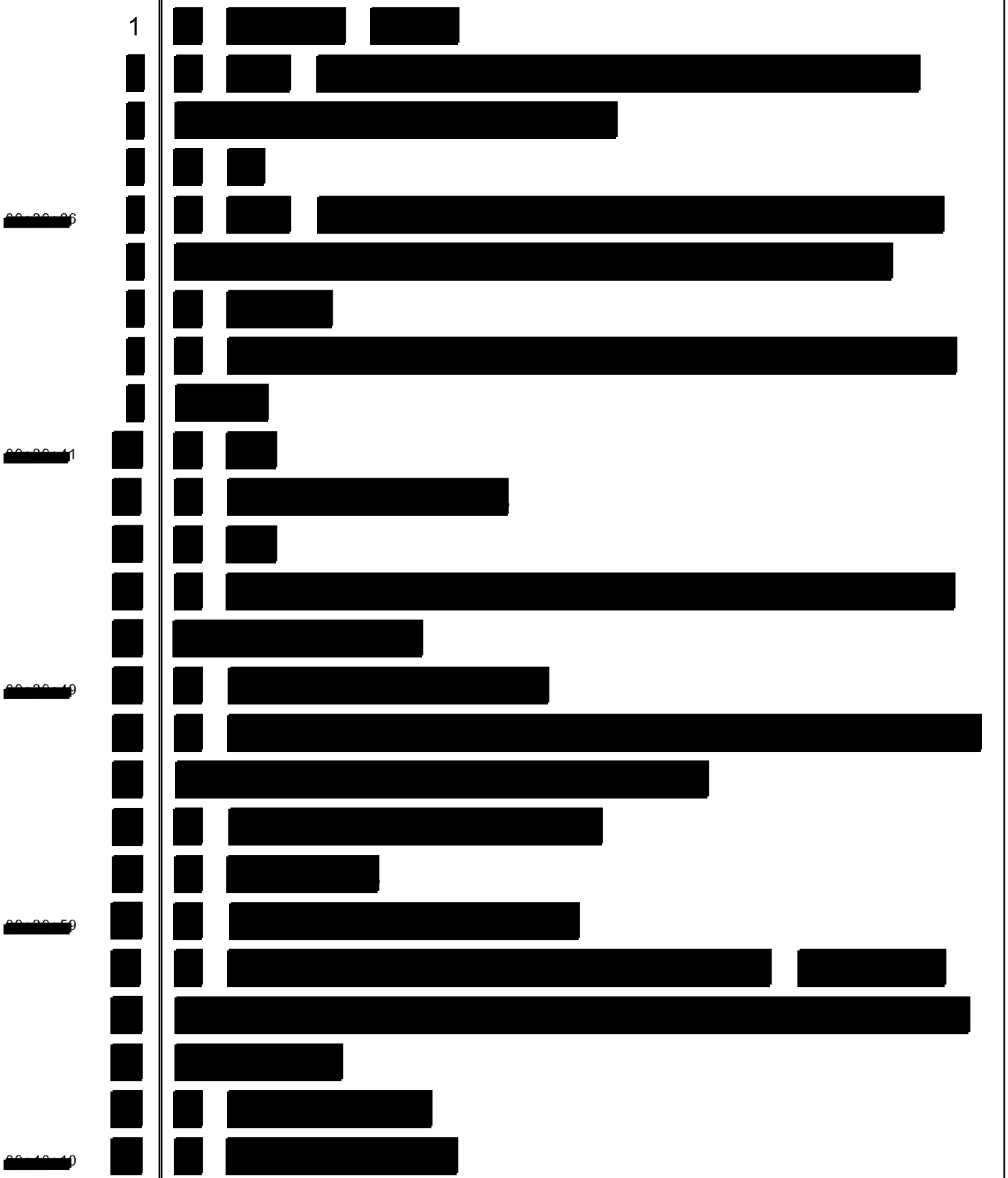

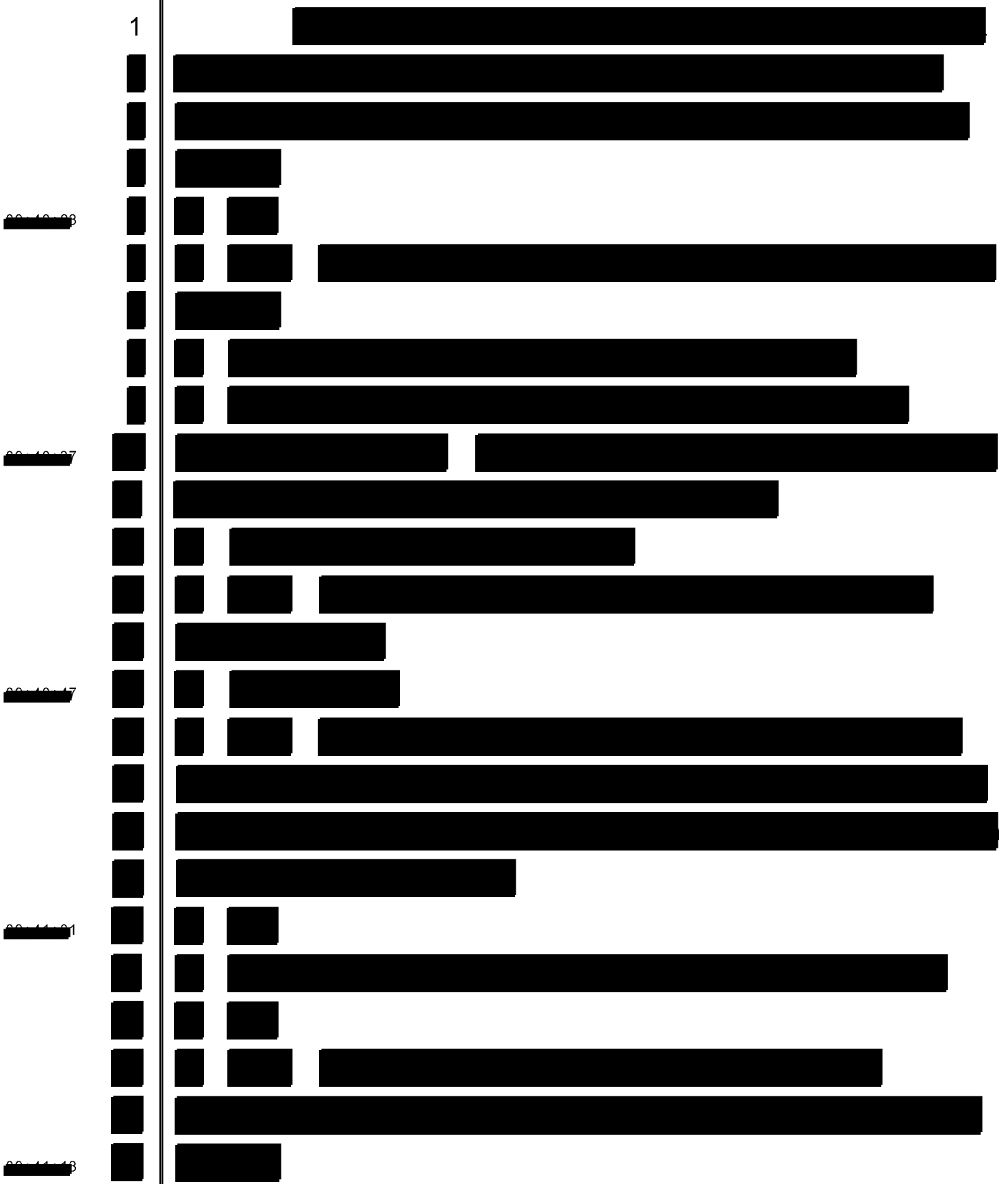

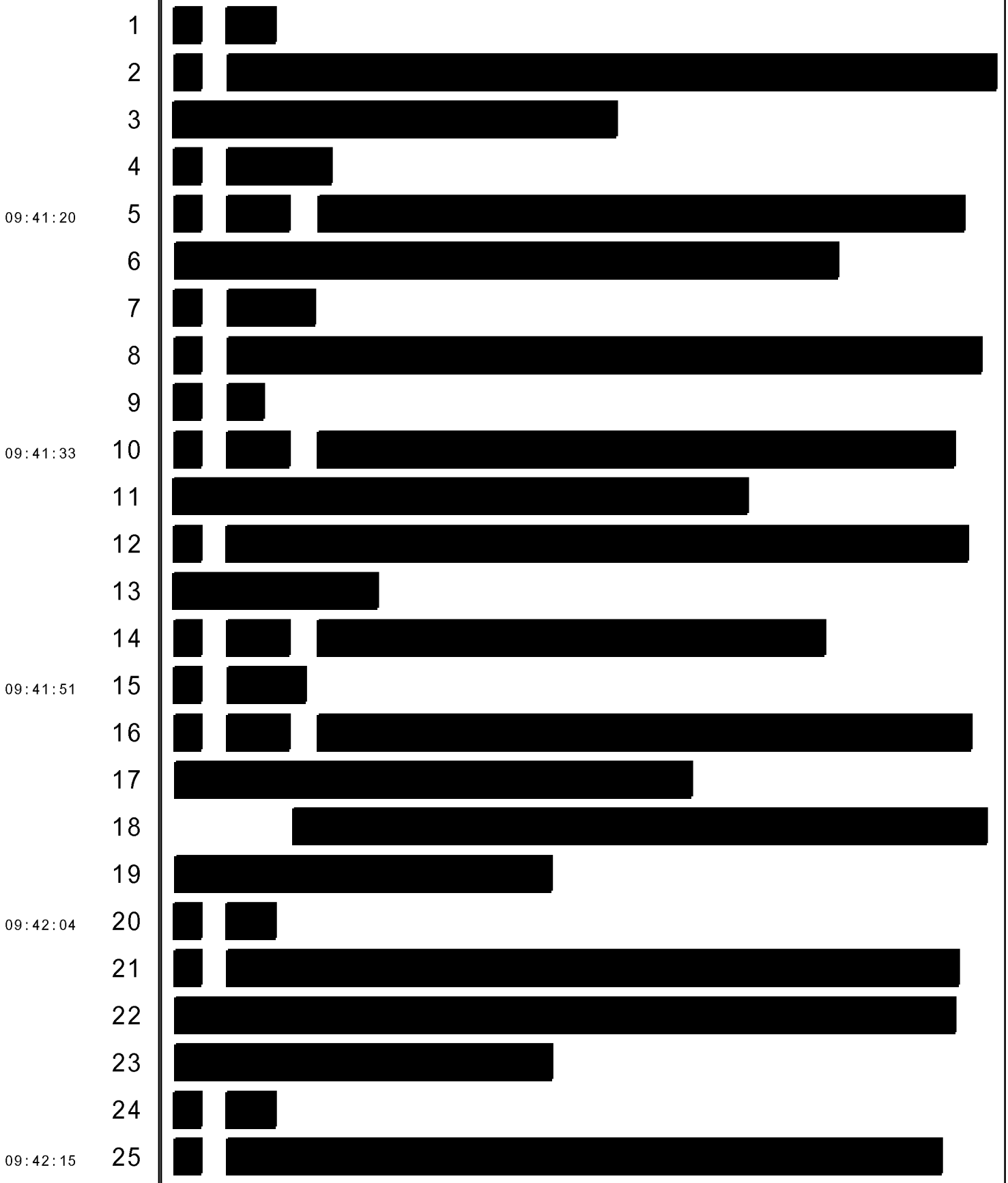
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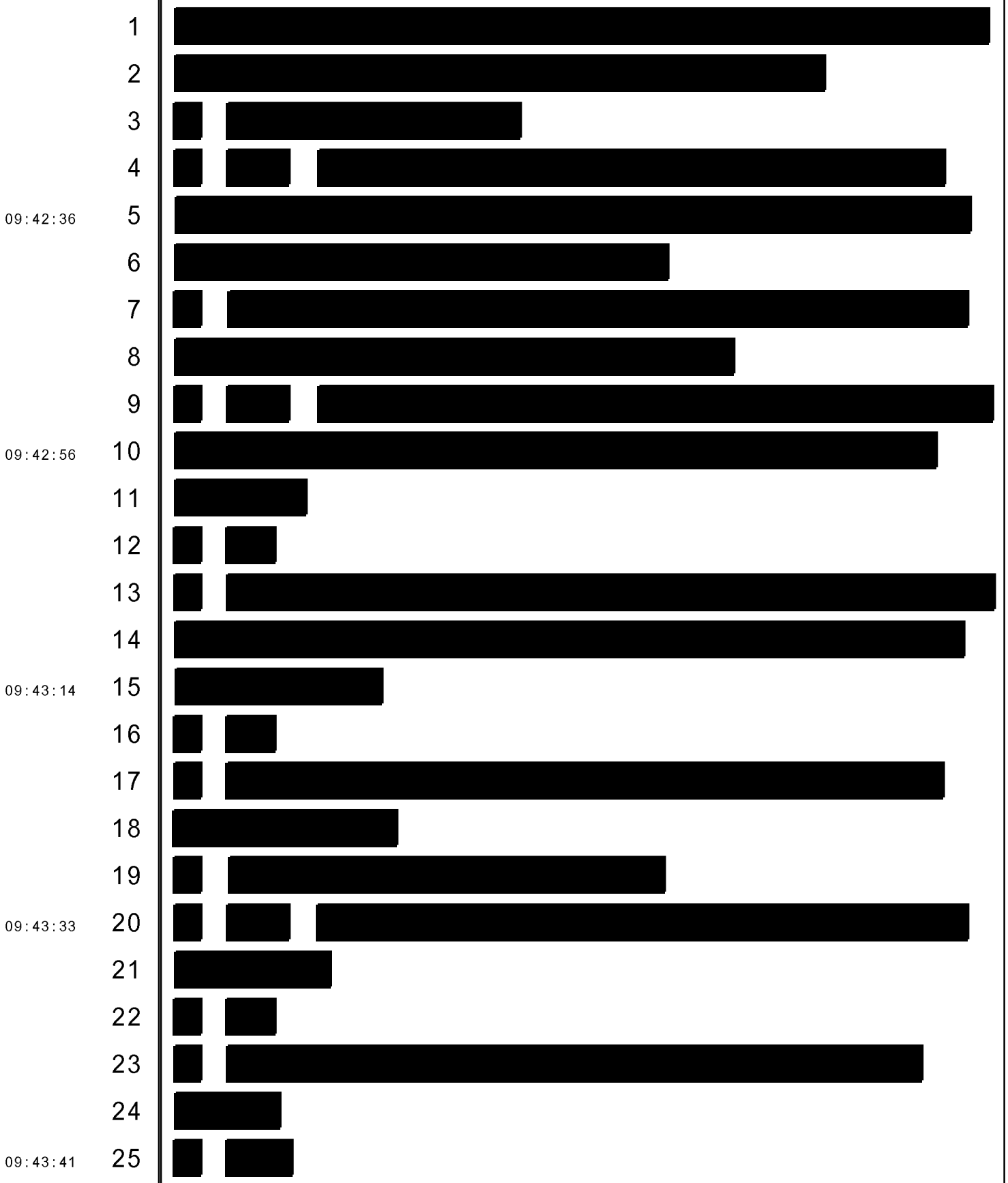
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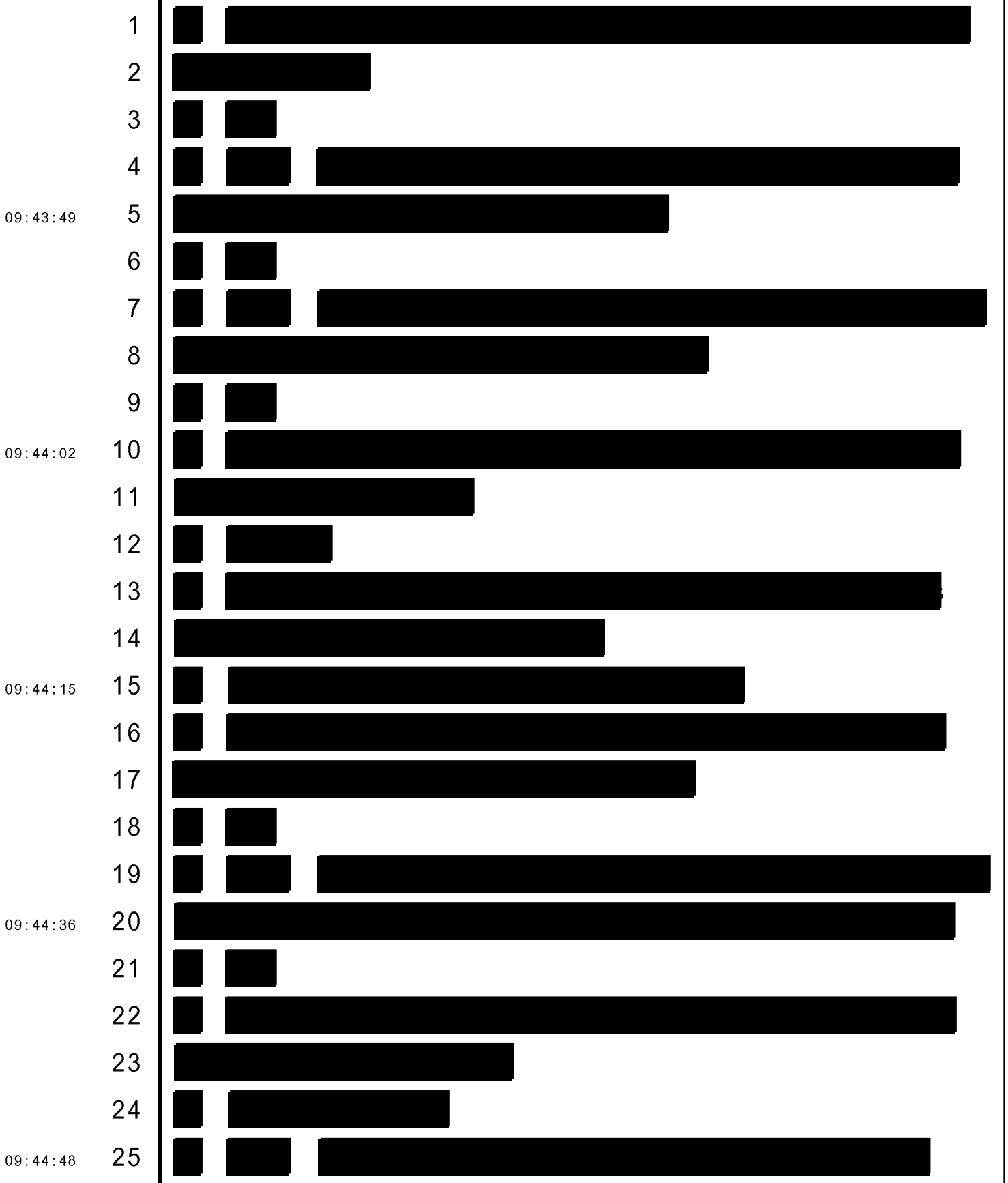
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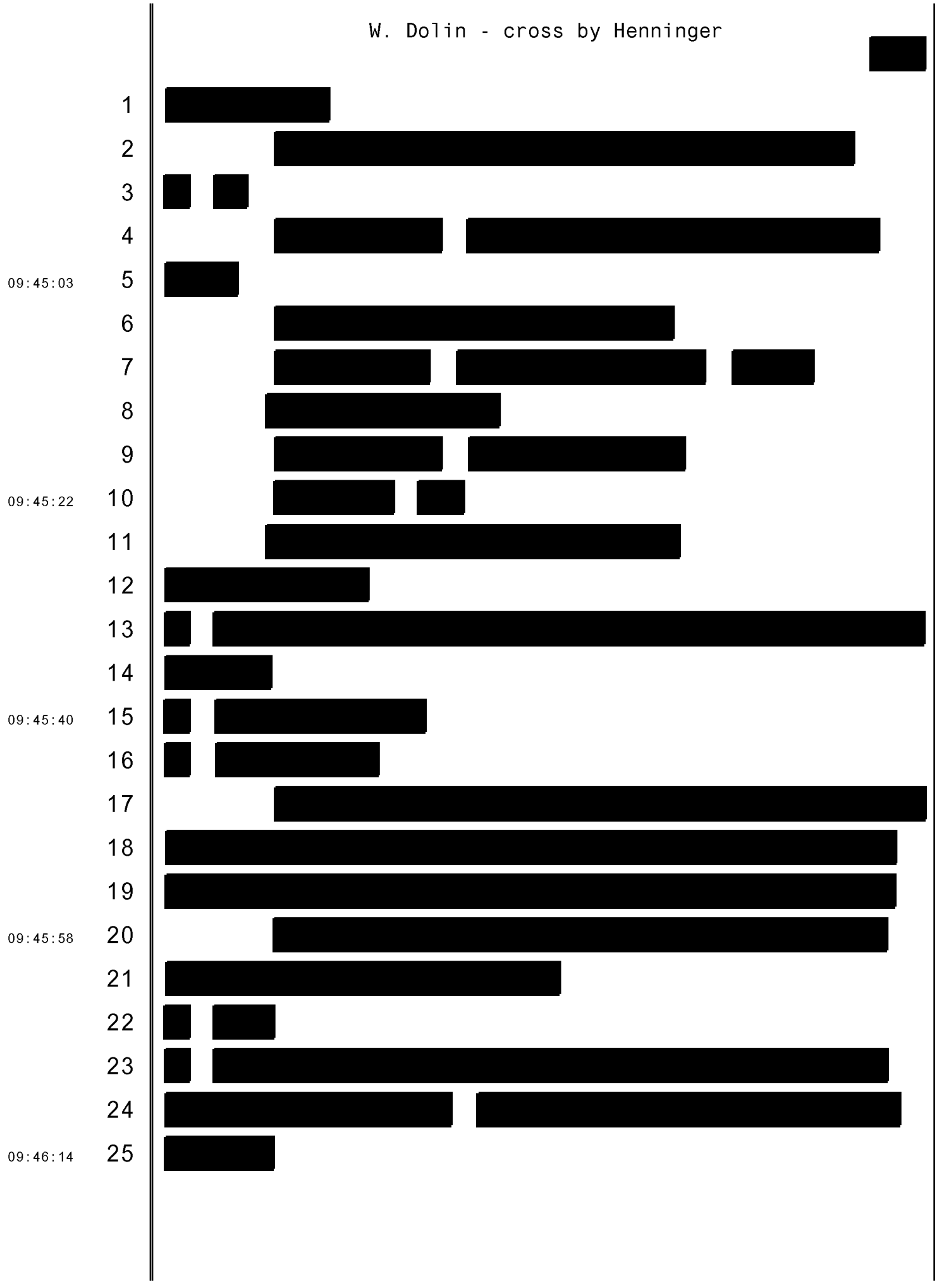
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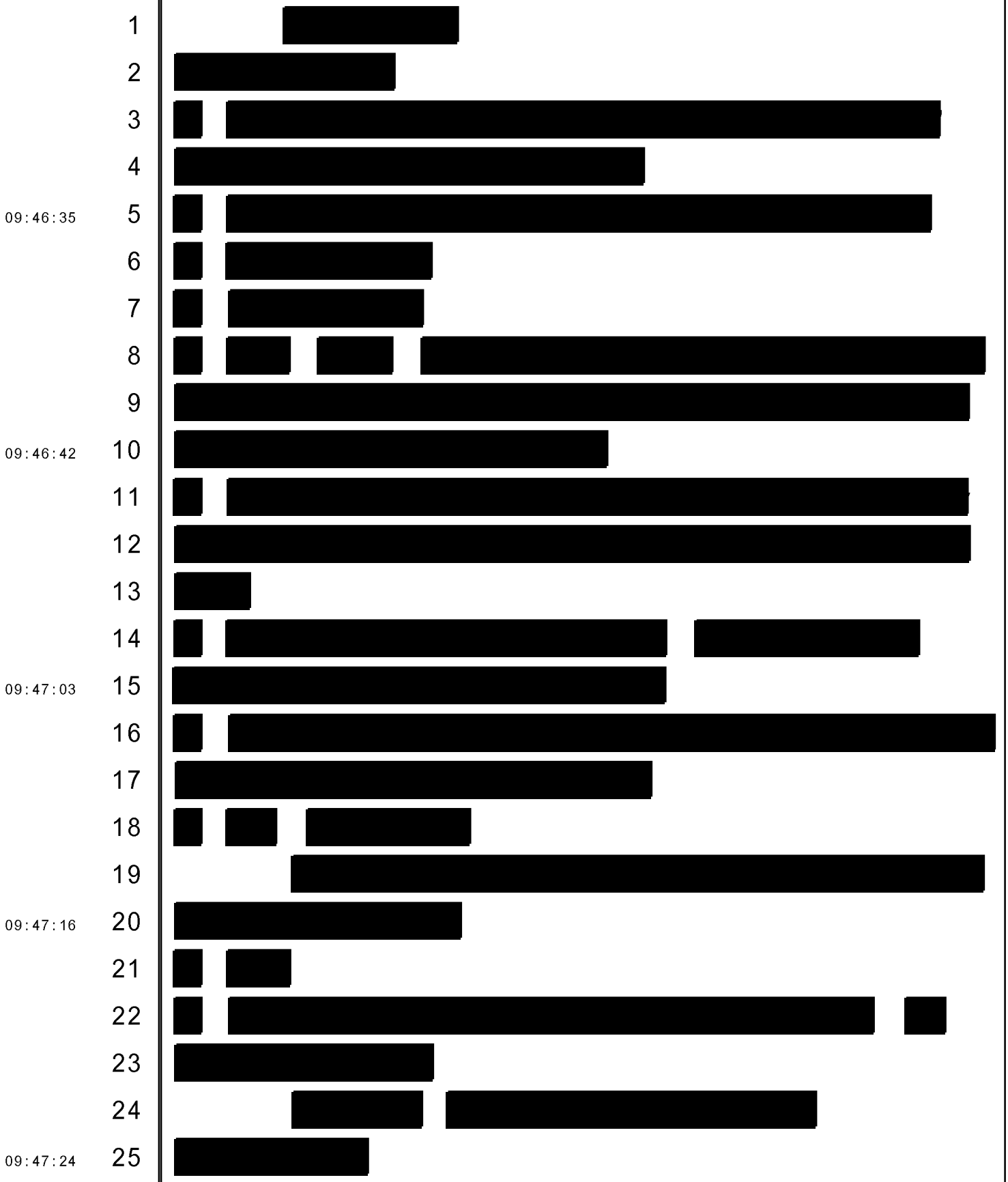
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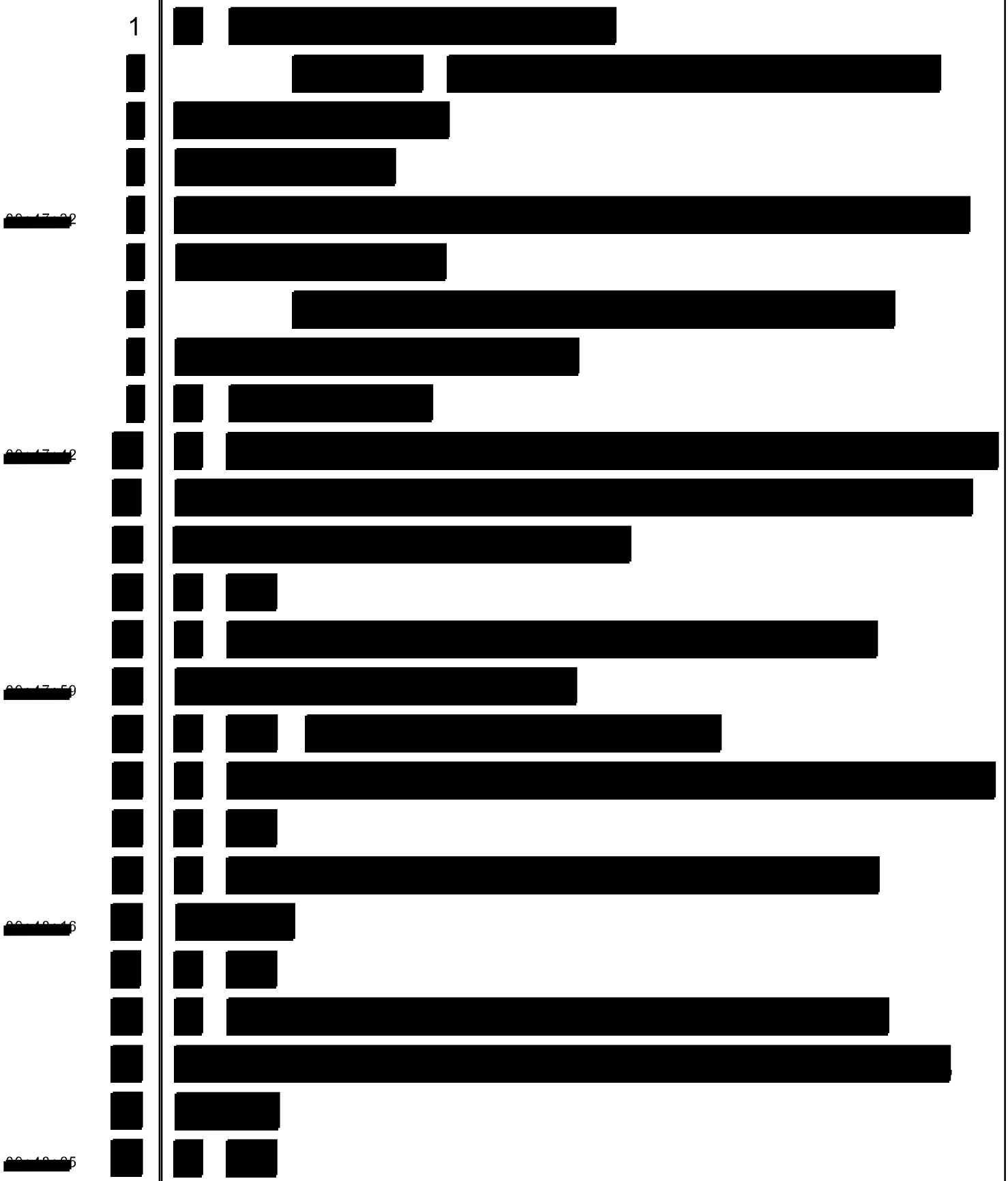

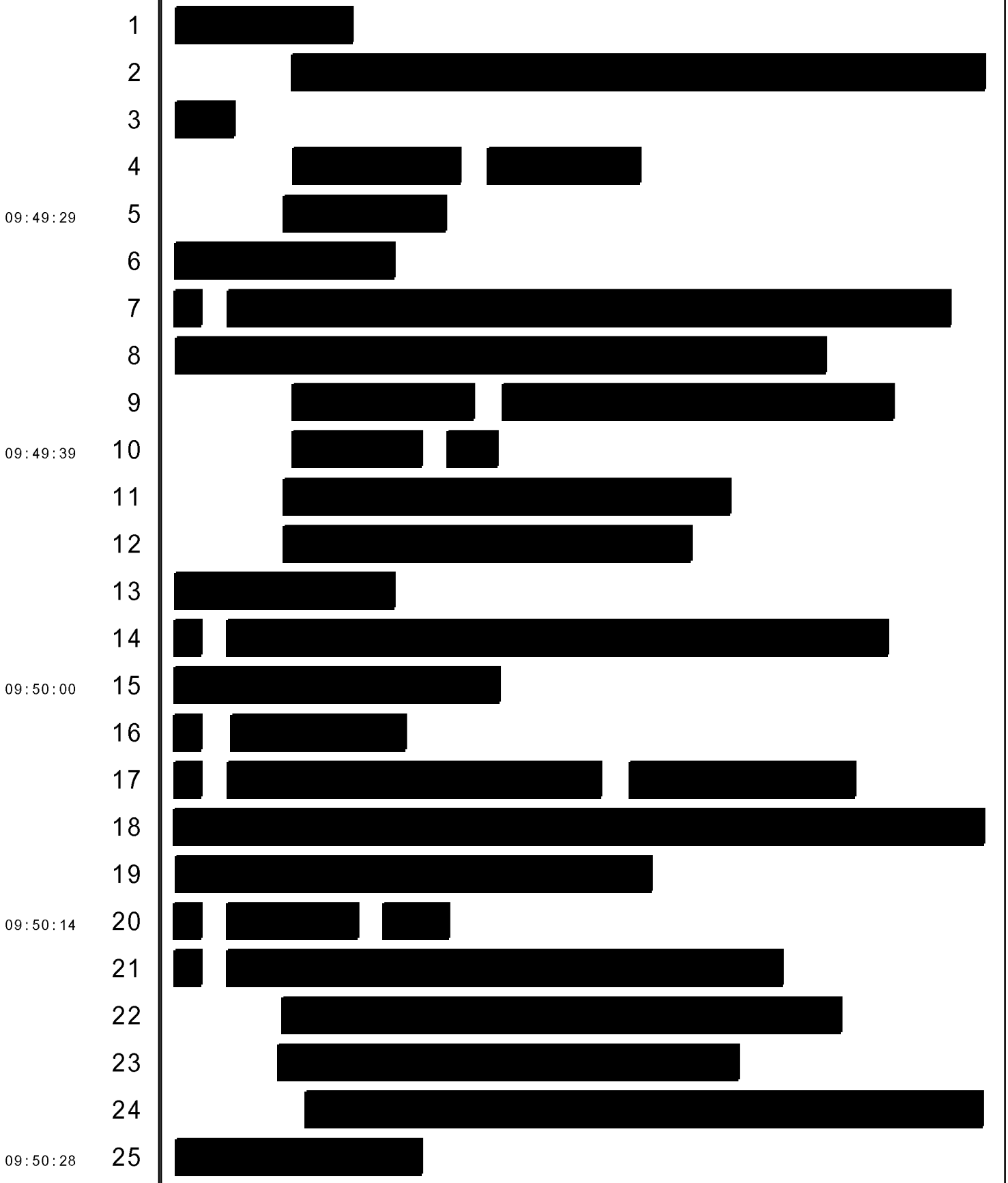
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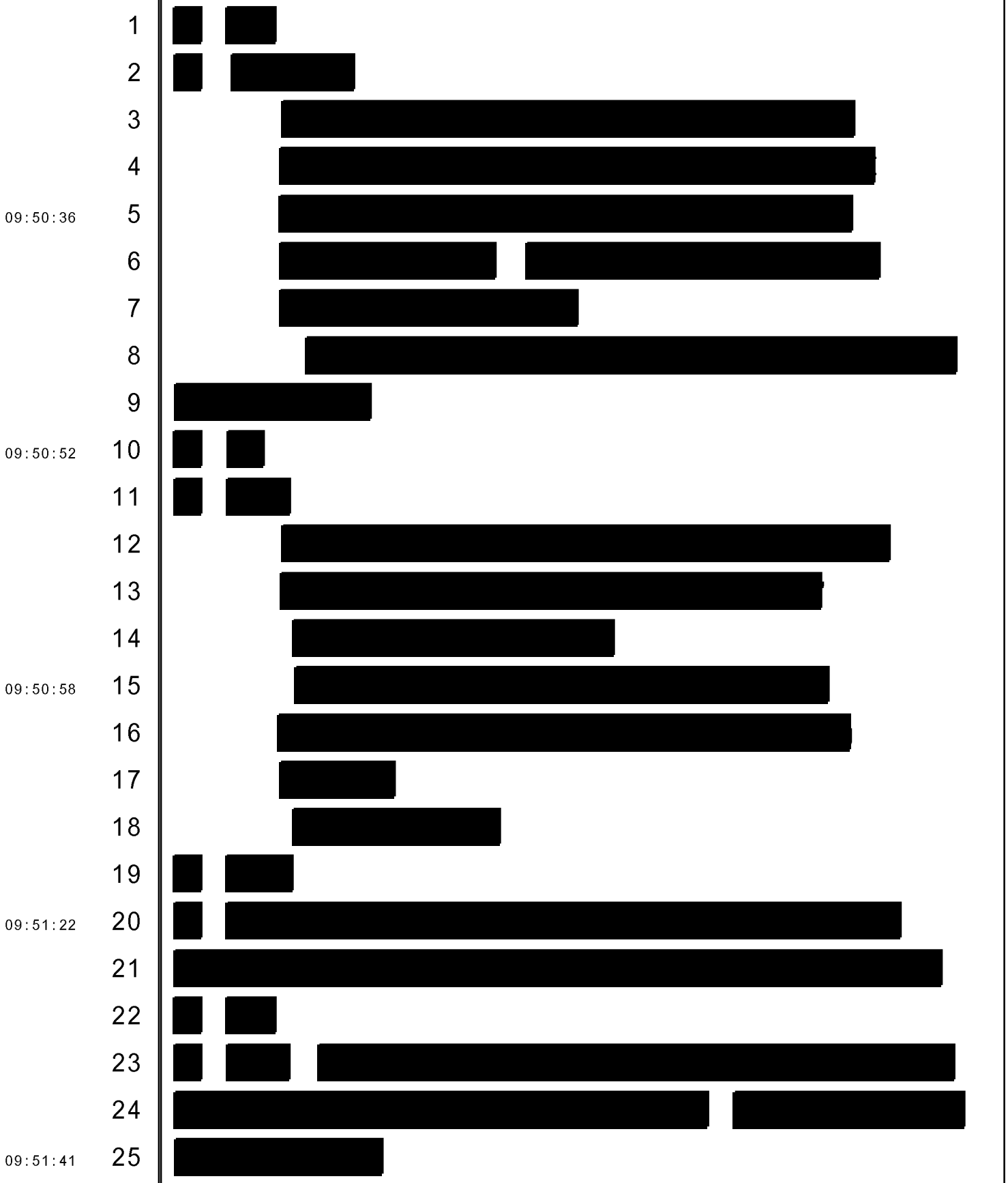
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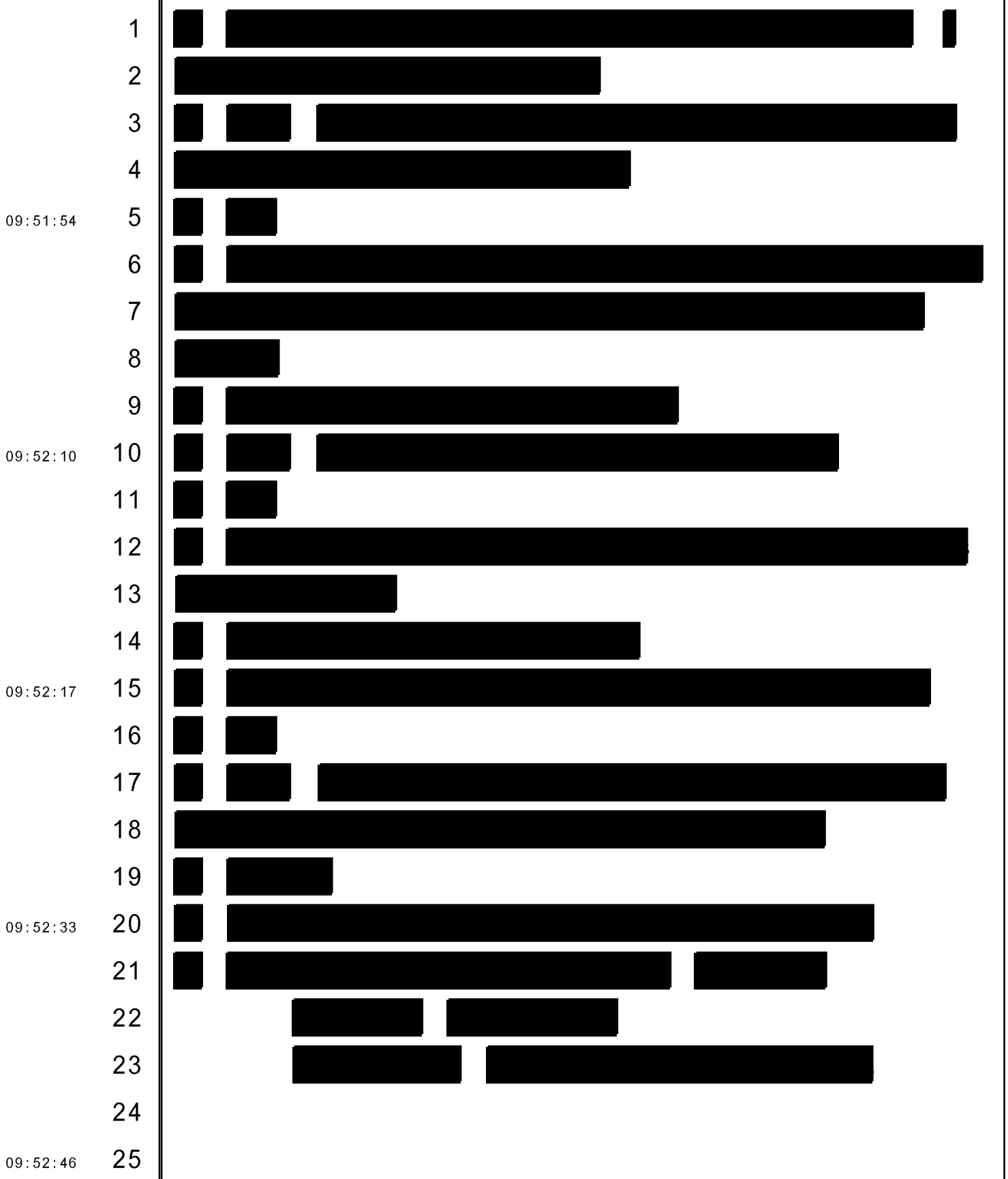
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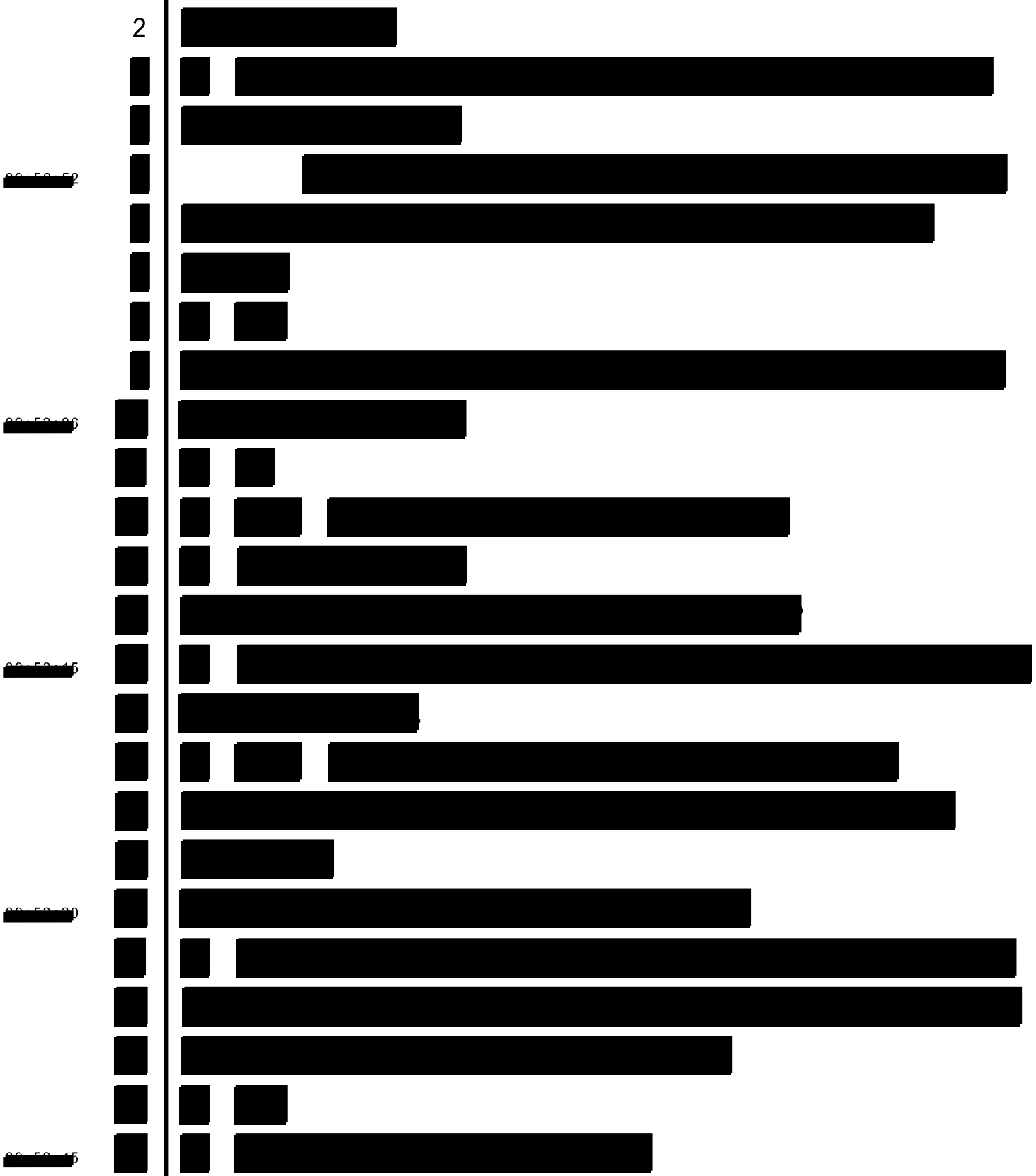
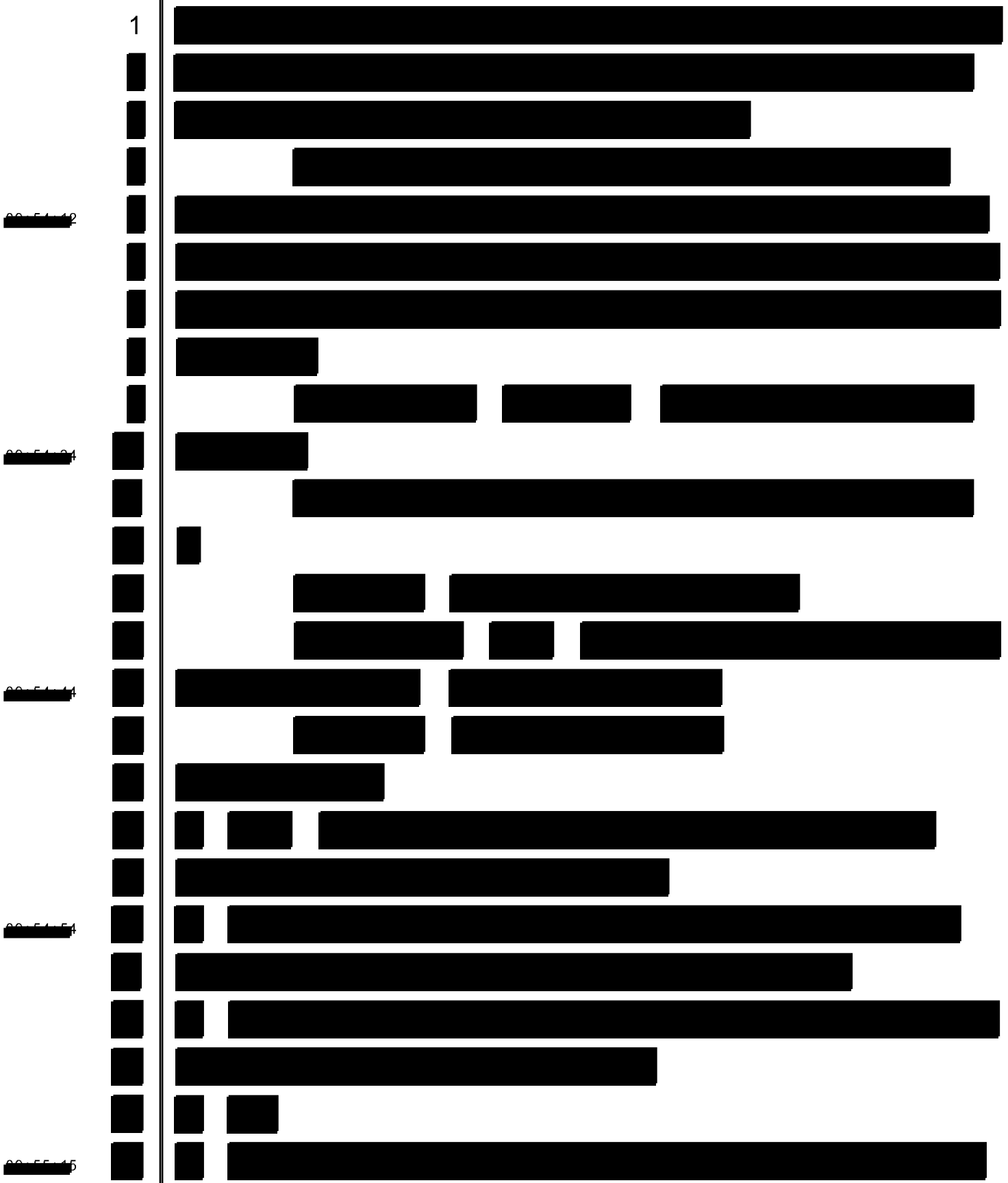
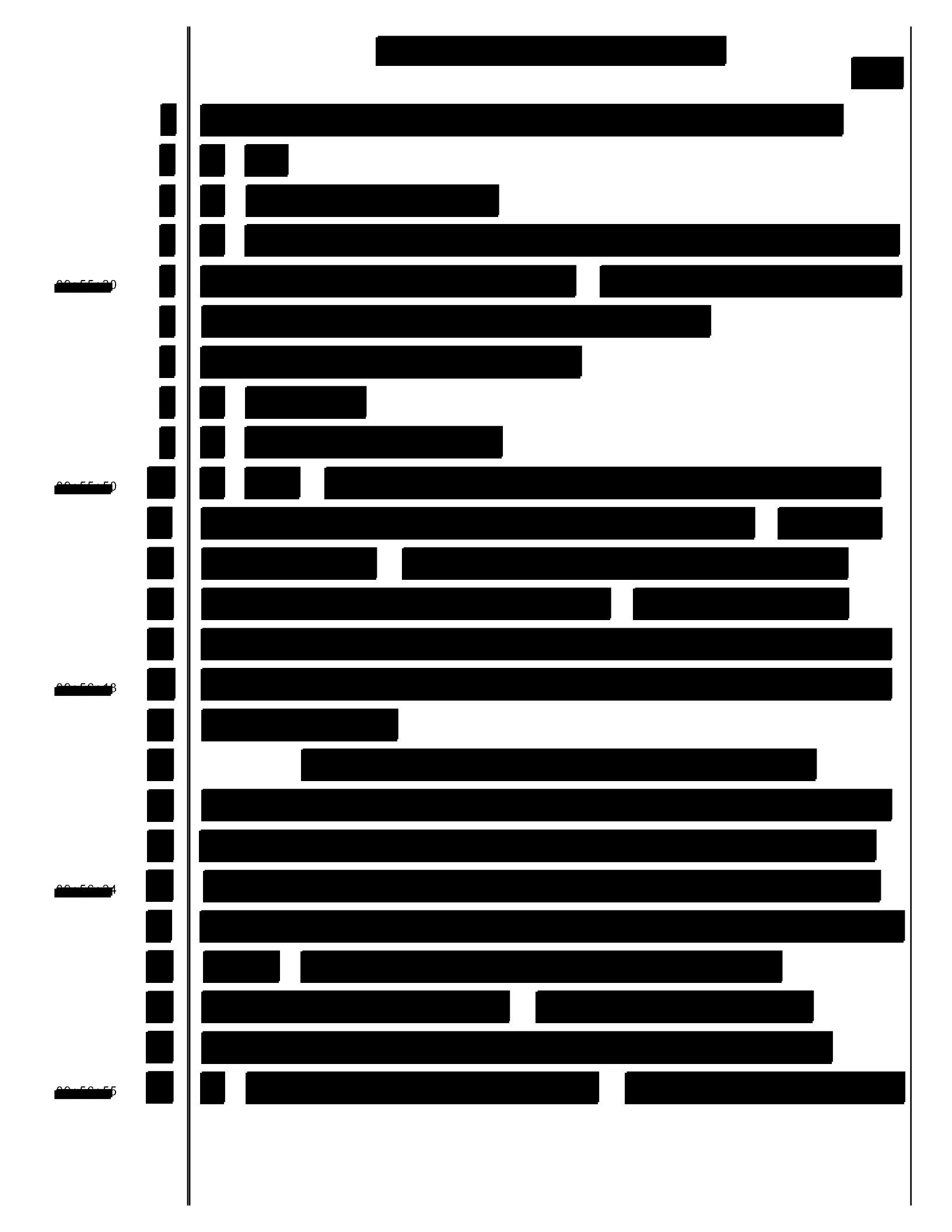
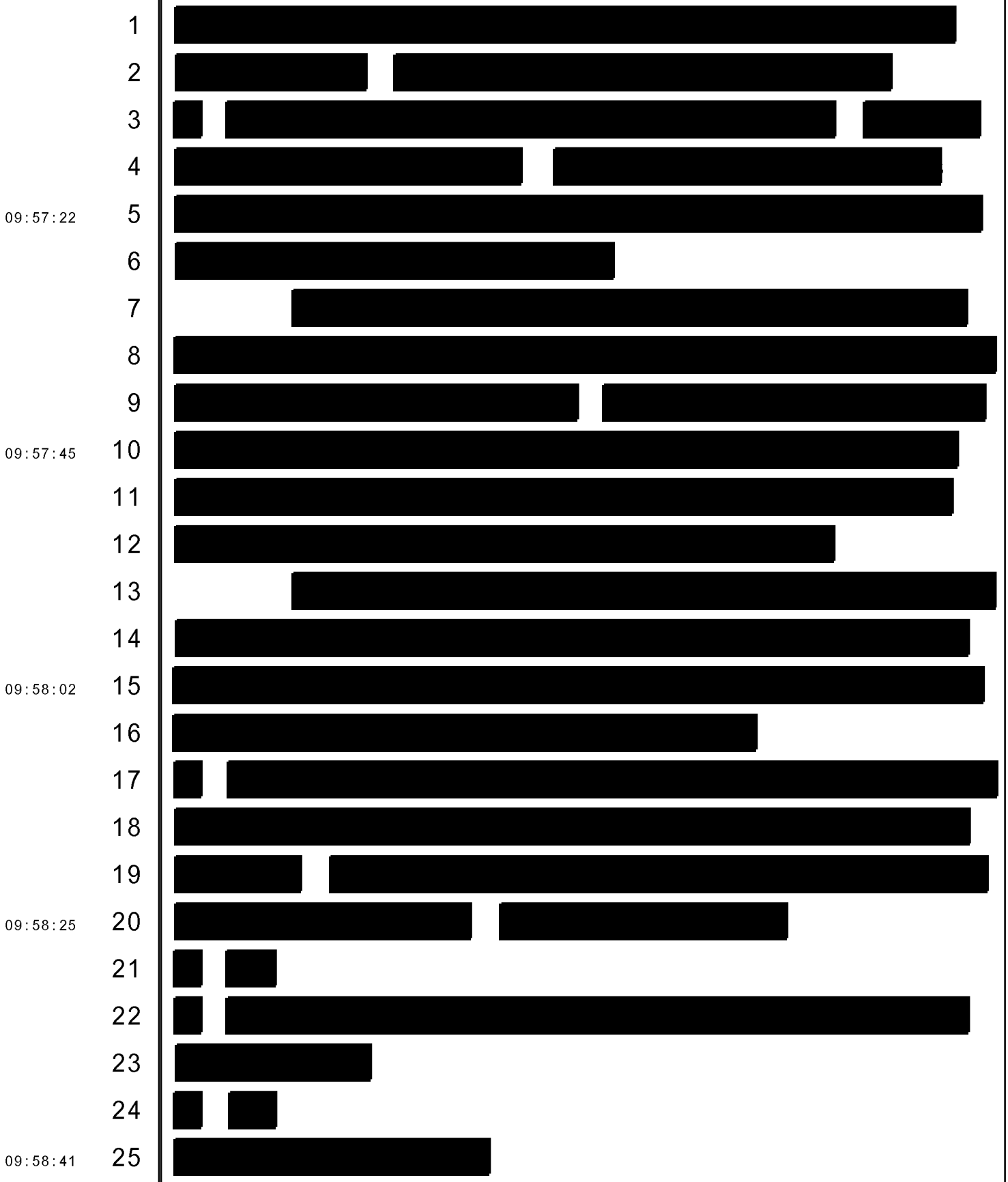
REDIRECT EXAMINATION





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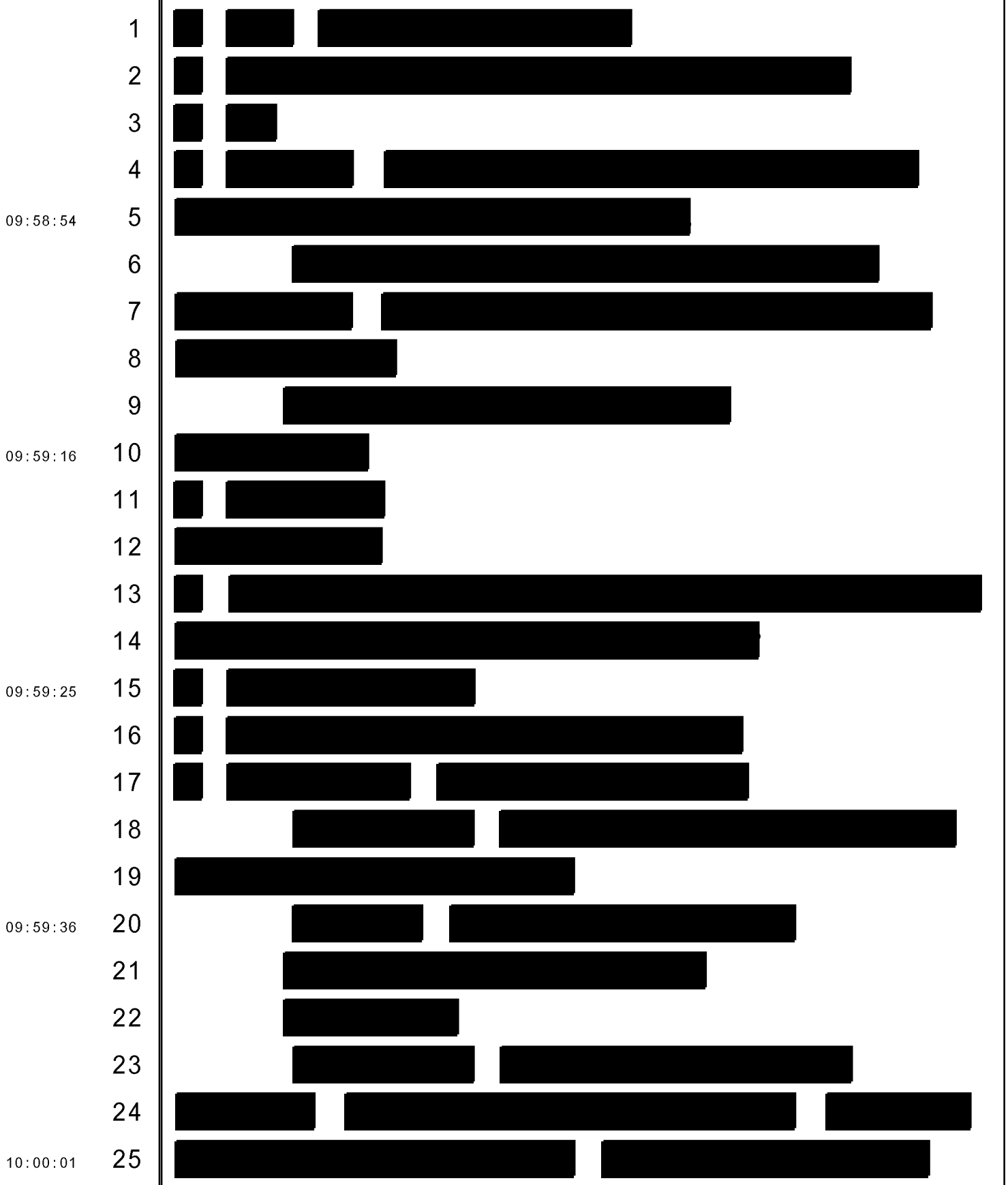
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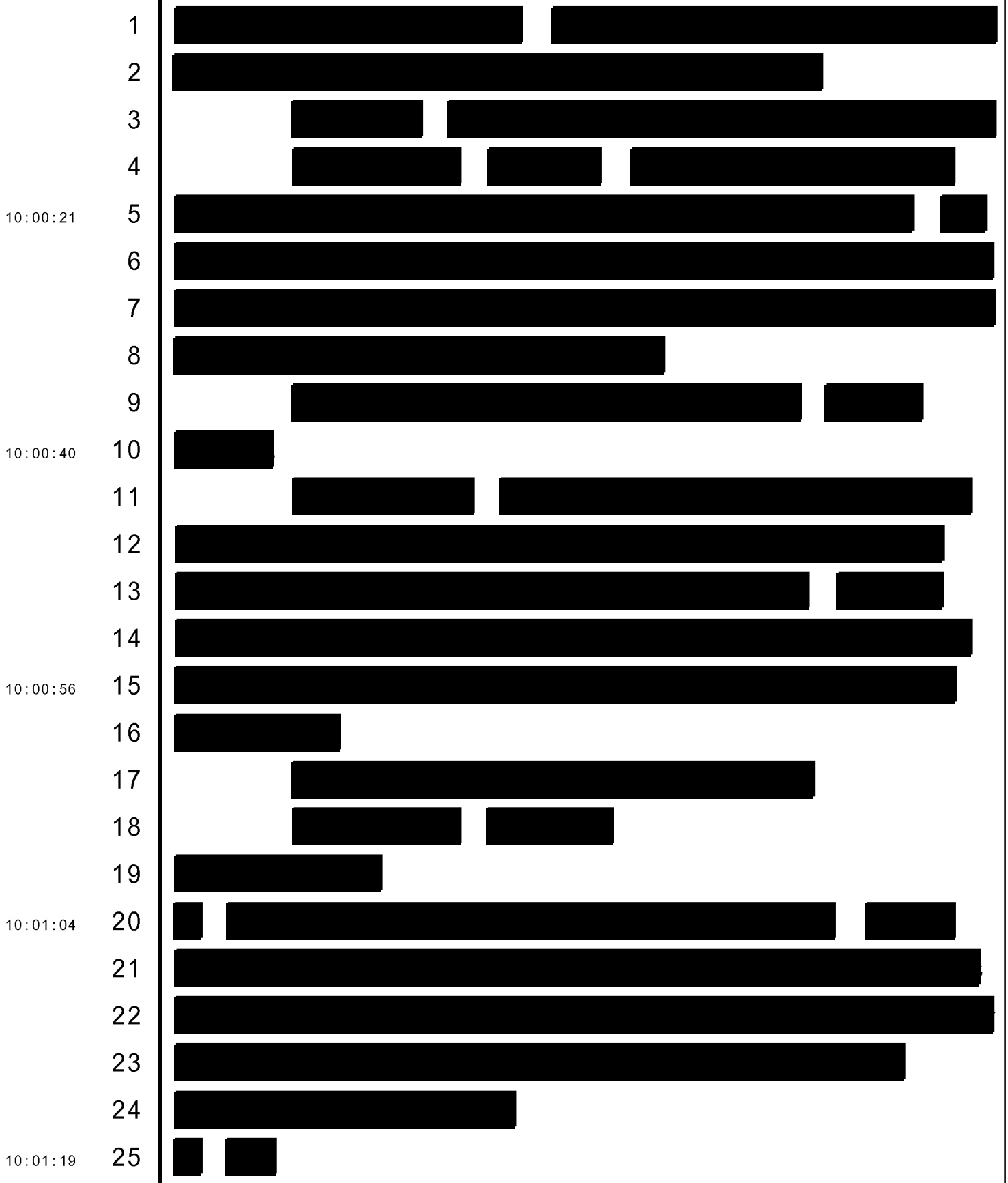
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THE WITNESS: Excuse me. Do you need this back (indicating)?

MS. HENNINGER: You can leave it up there. I'll get it, Mrs. Dolin.

THE COURT: Leave everything there, ma'am.

MR. RAPOPORT: This is just about read, but yesterday, Your Honor, you admitted into evidence life expectancy tables, I would just like to publish the life expectancy of a 57-year old male at this time. Takes one second.

THE COURT: All right.

MR. RAPOPORT: All right. According to a table of mortality, admitted in evidence, the life expectancy of a male person aged 57 years is 24 years.

Thank you, ladies and gentlemen.

Now Exhibit 2.

(Exhibit published to the jury.)

MR. RAPOPORT: Your Honor, ladies and gentlemen, we rest our case.

10:15:15 THE COURT: All right. Ladies and gentlemen, we will take a brief recess now. You may step into the jury room, if you will.

(The following proceedings were had out of the presence of the jury in open court:)

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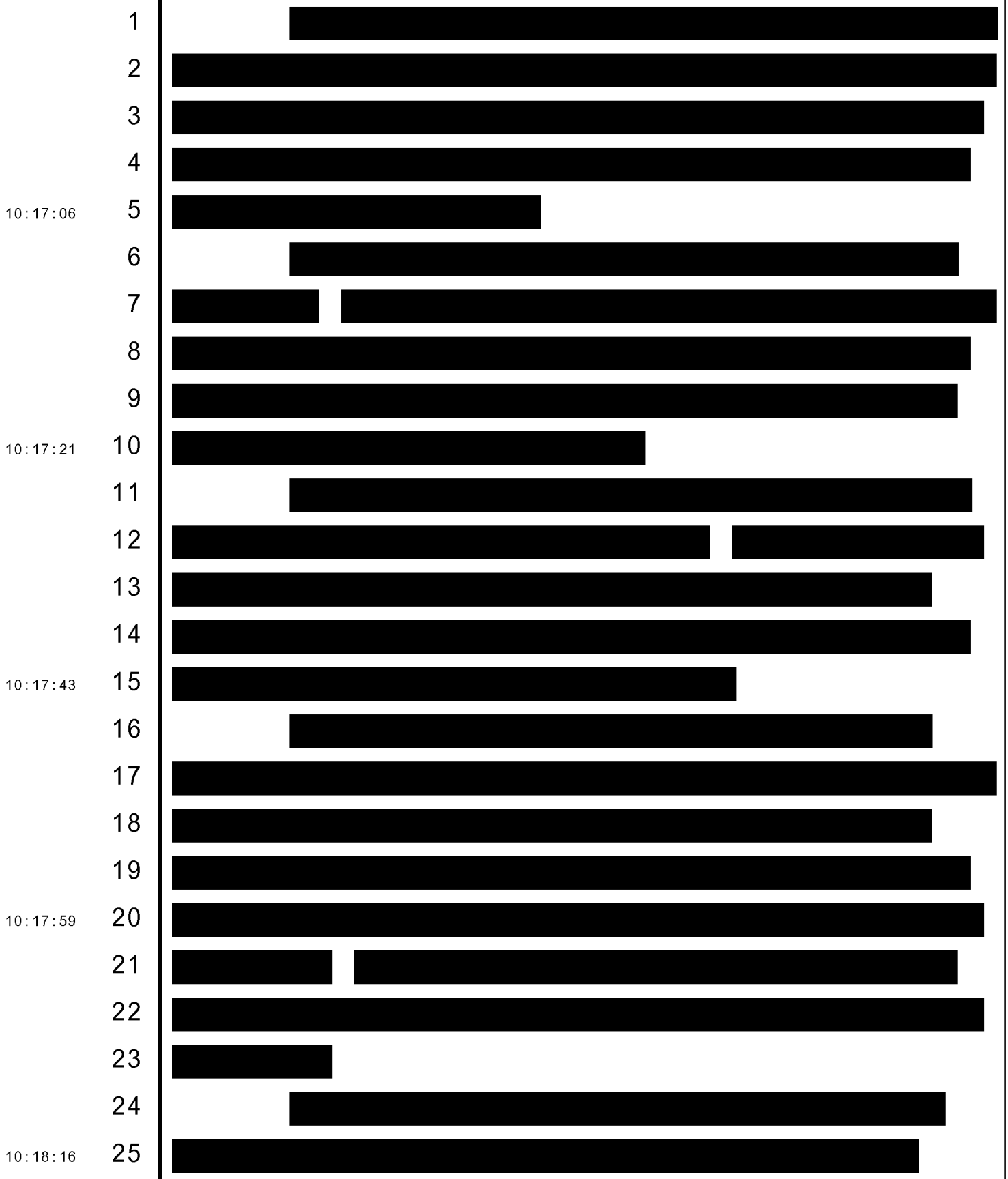
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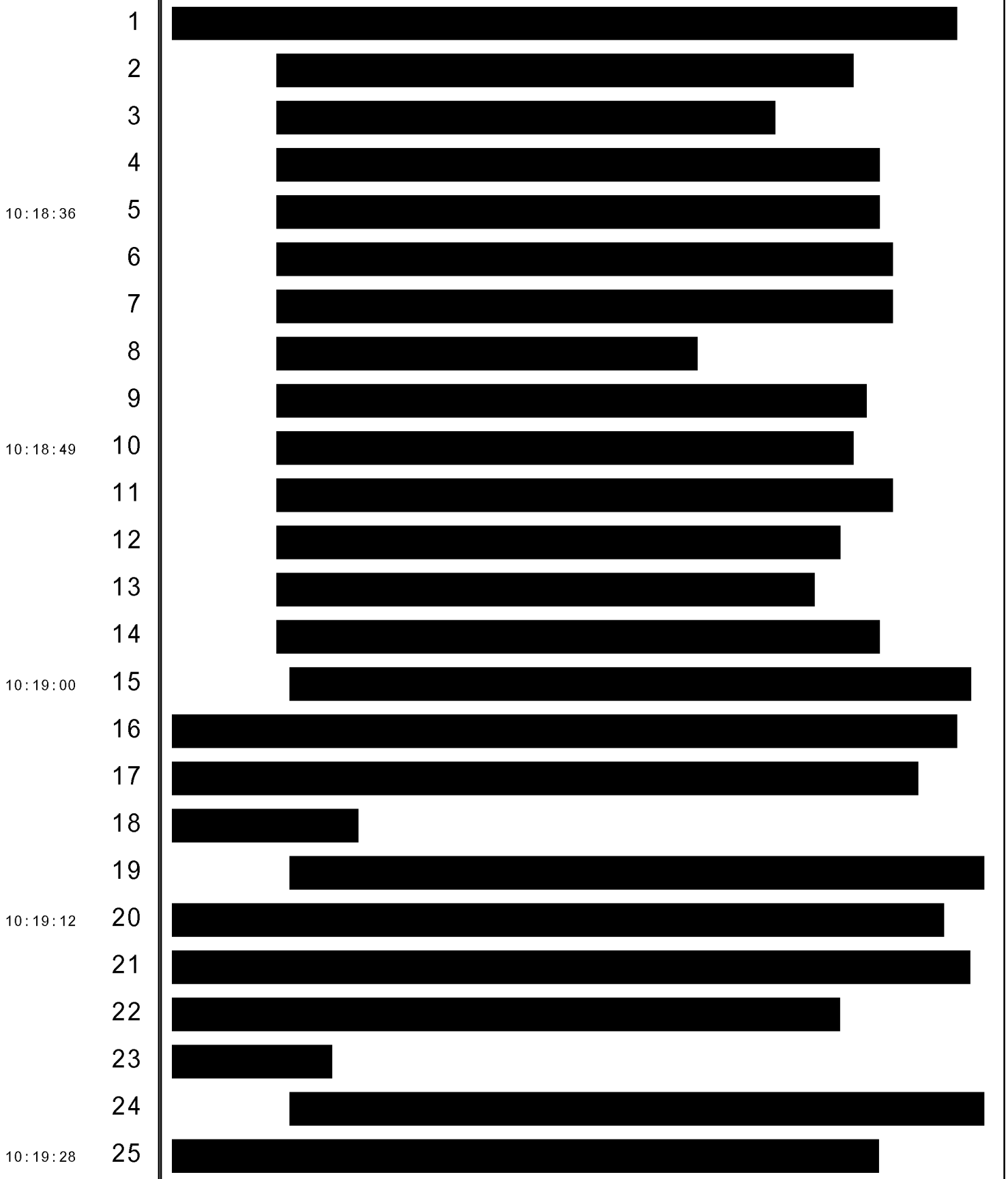
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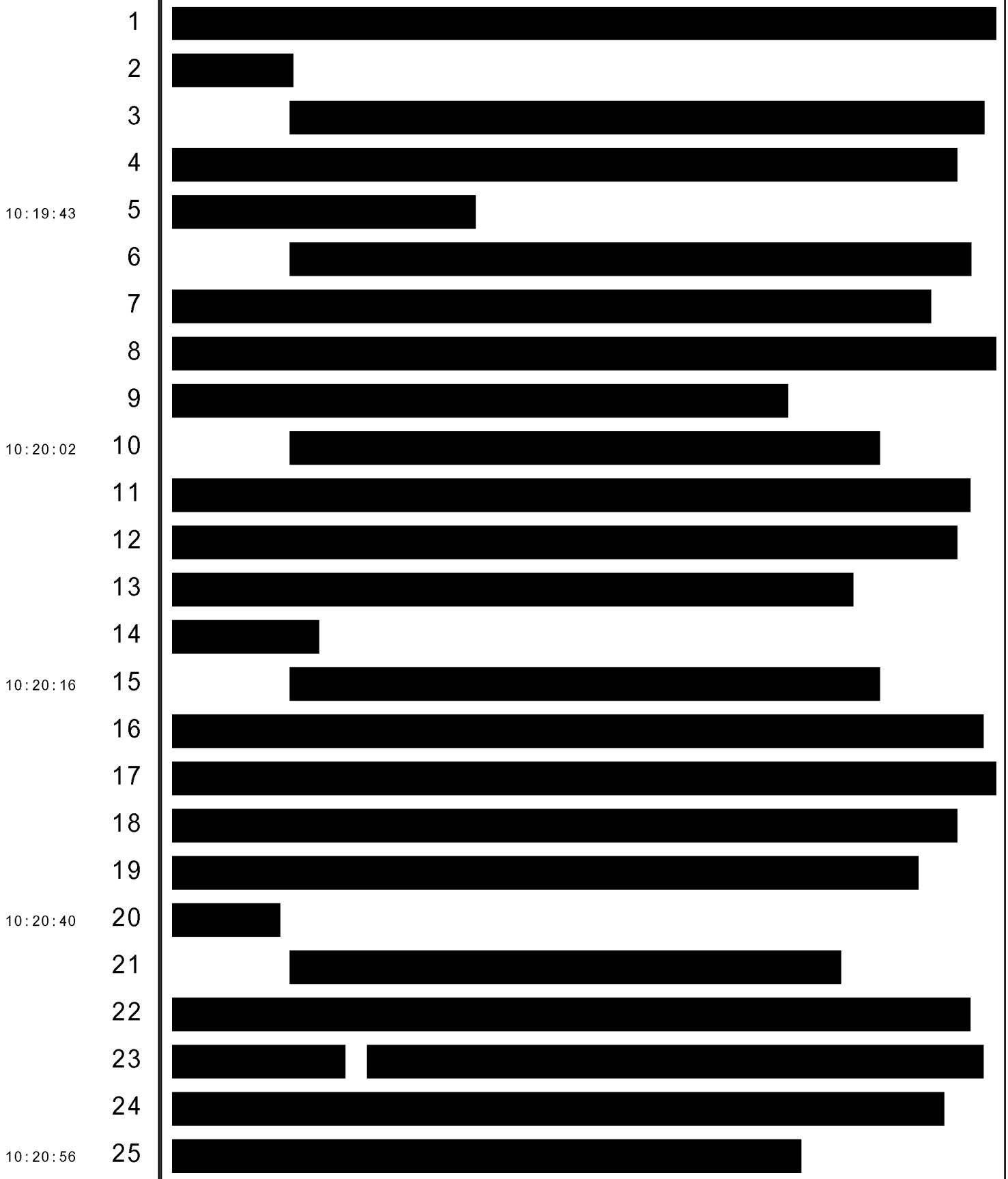
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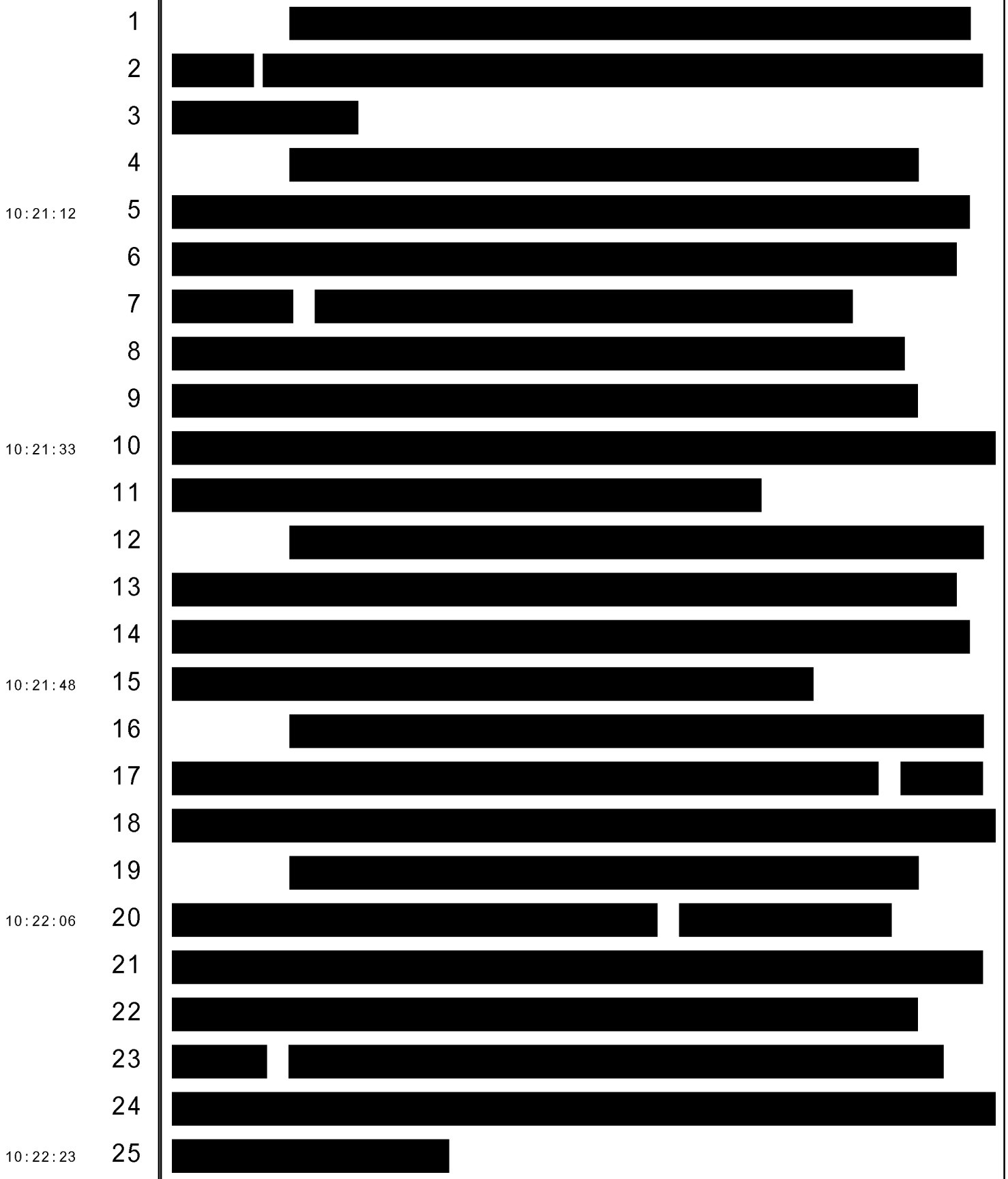
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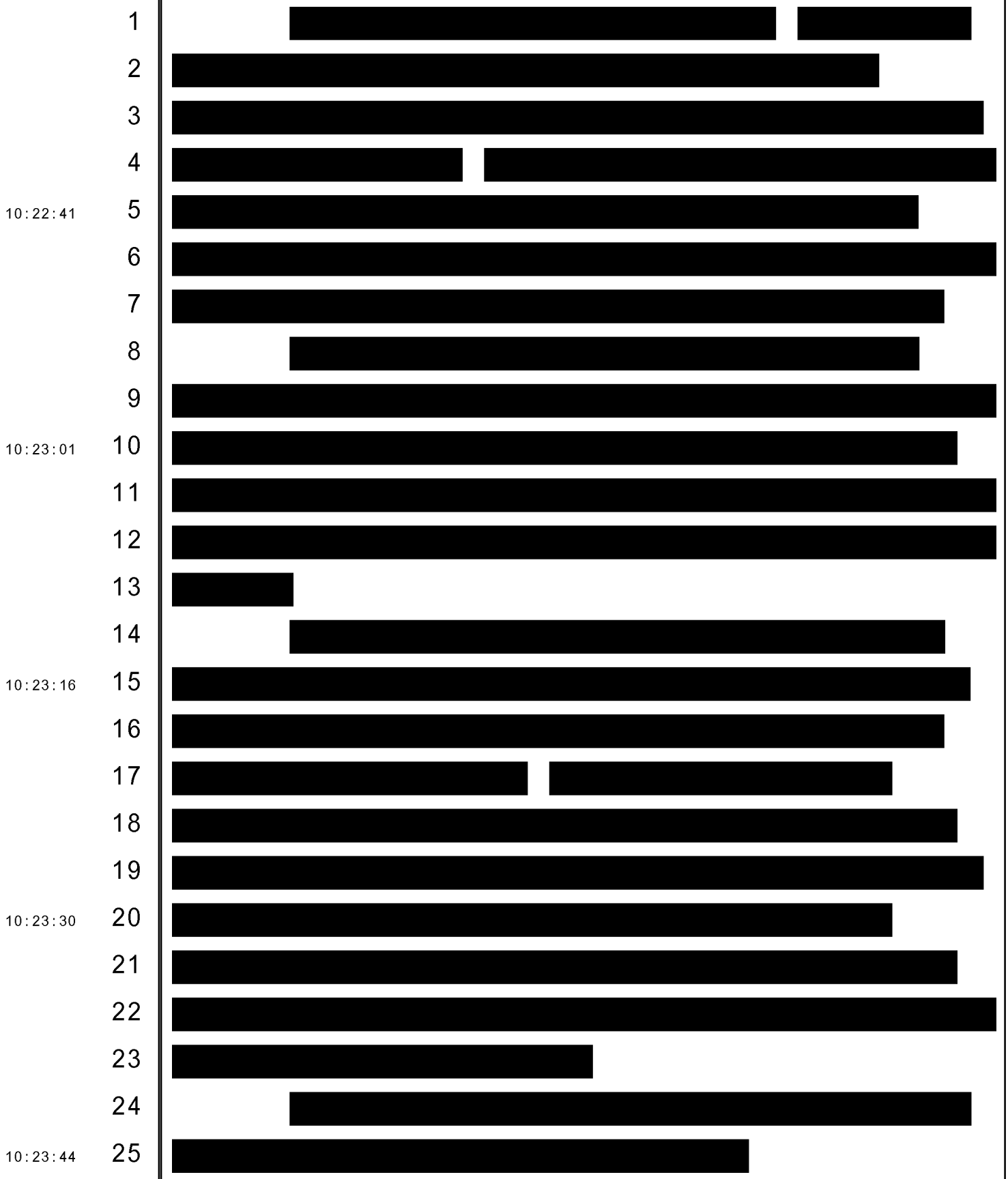
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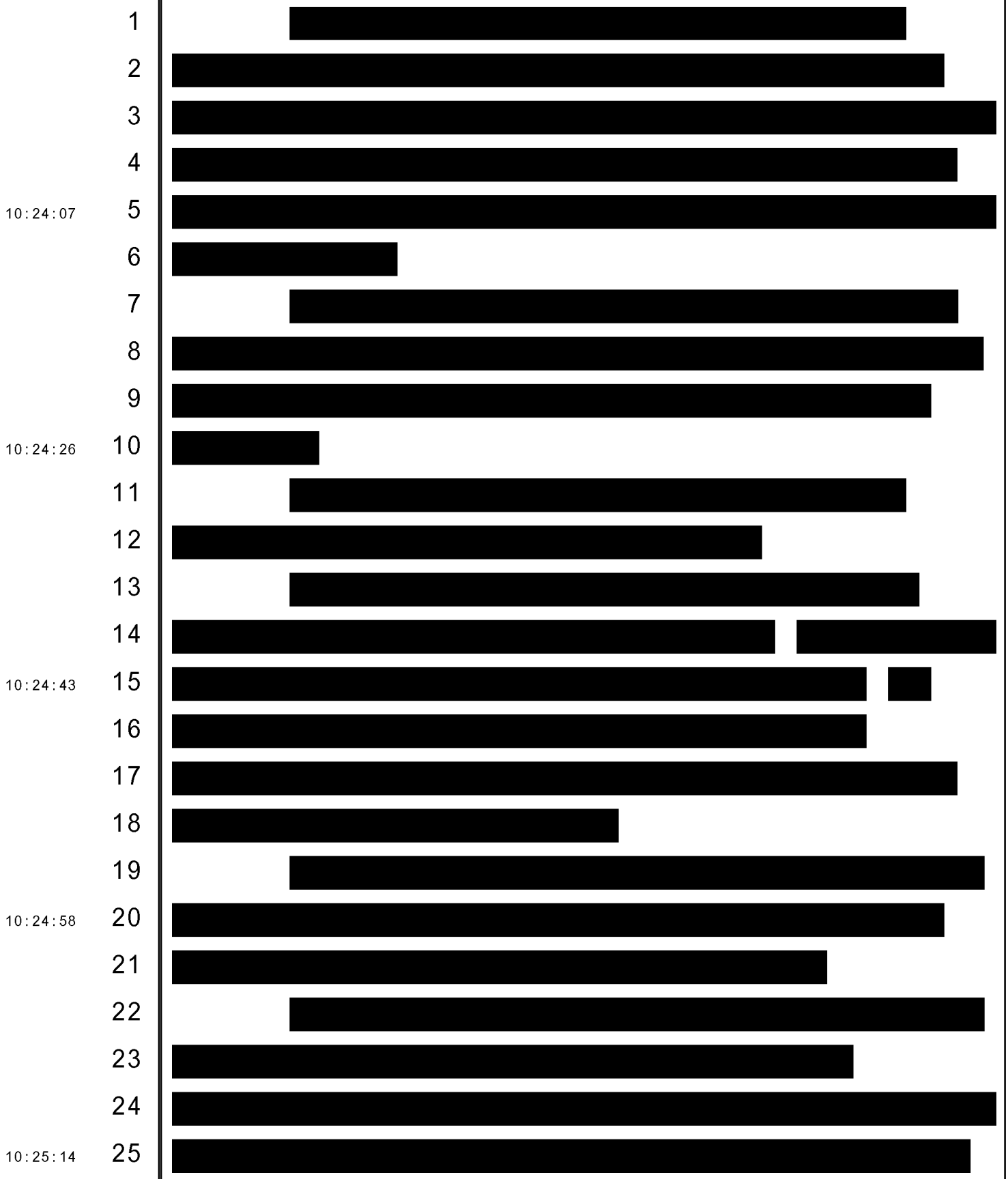
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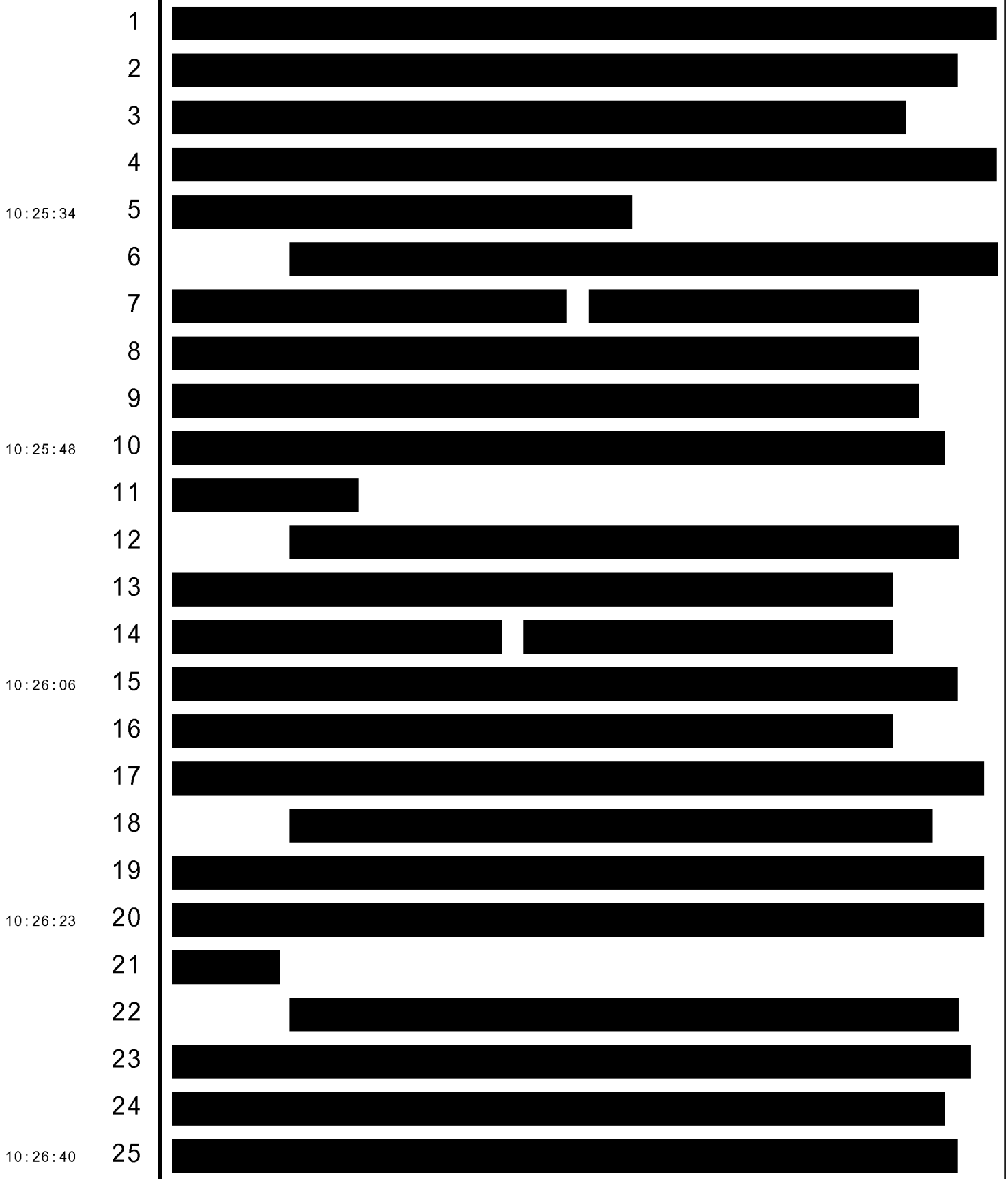
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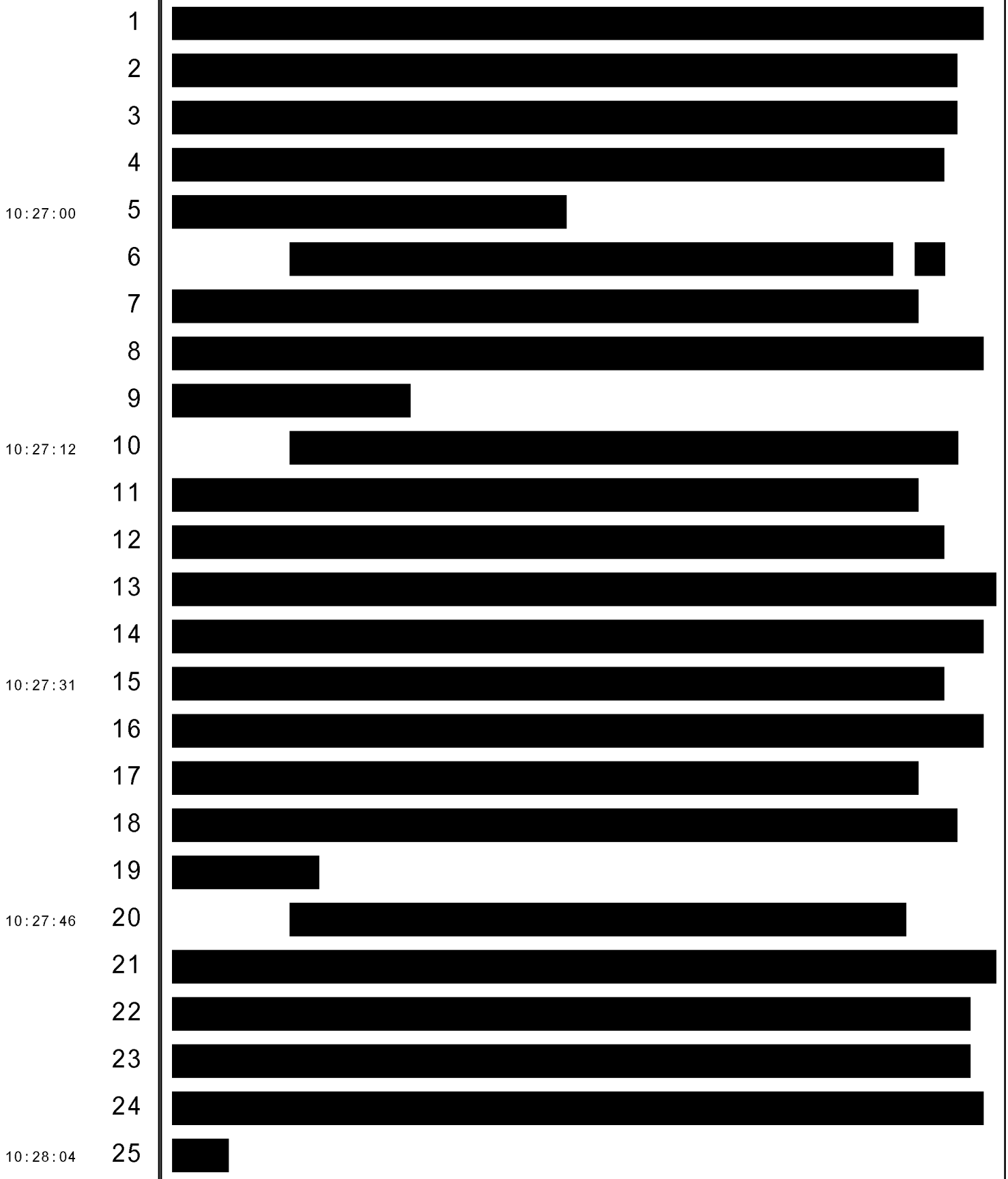
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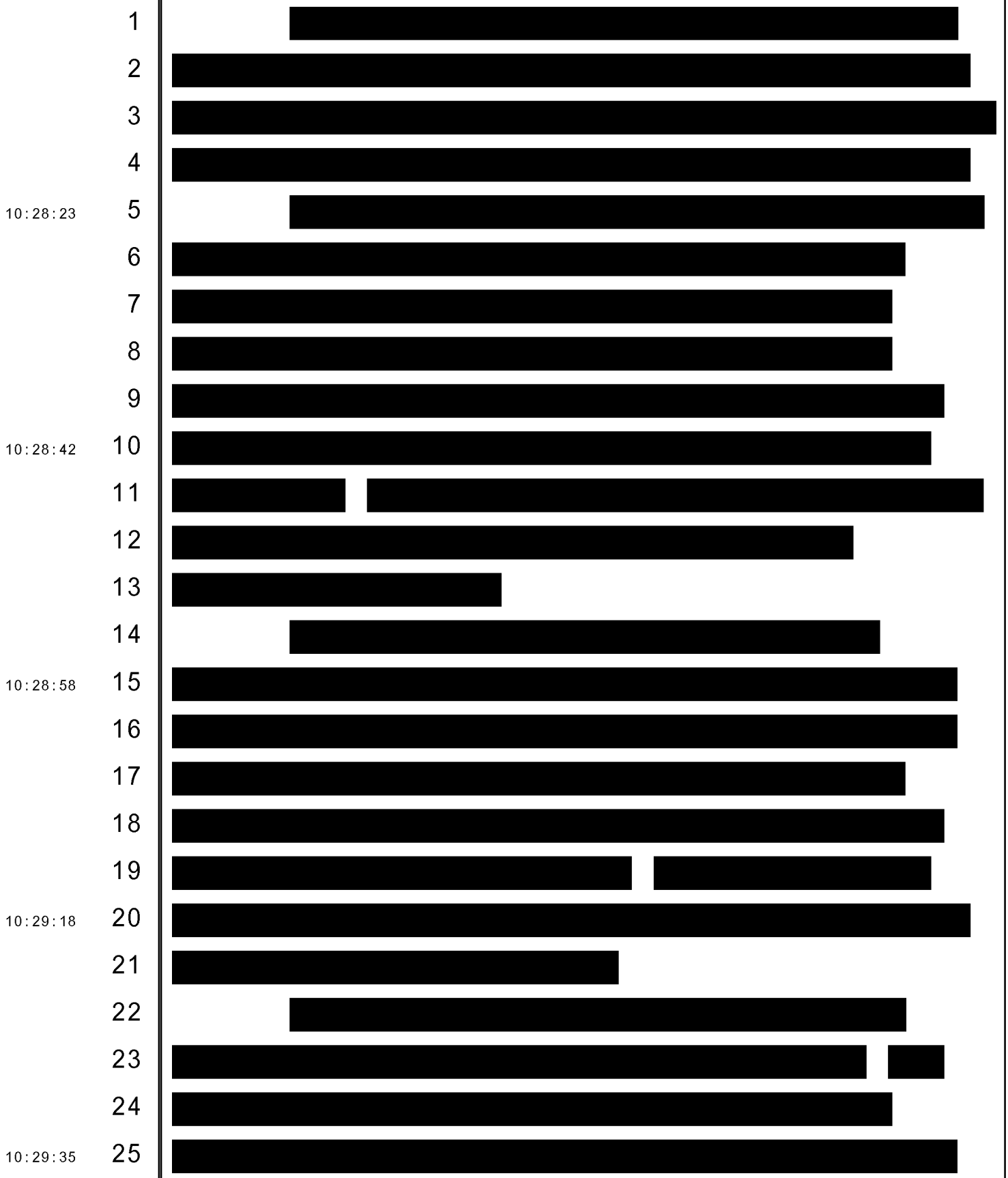
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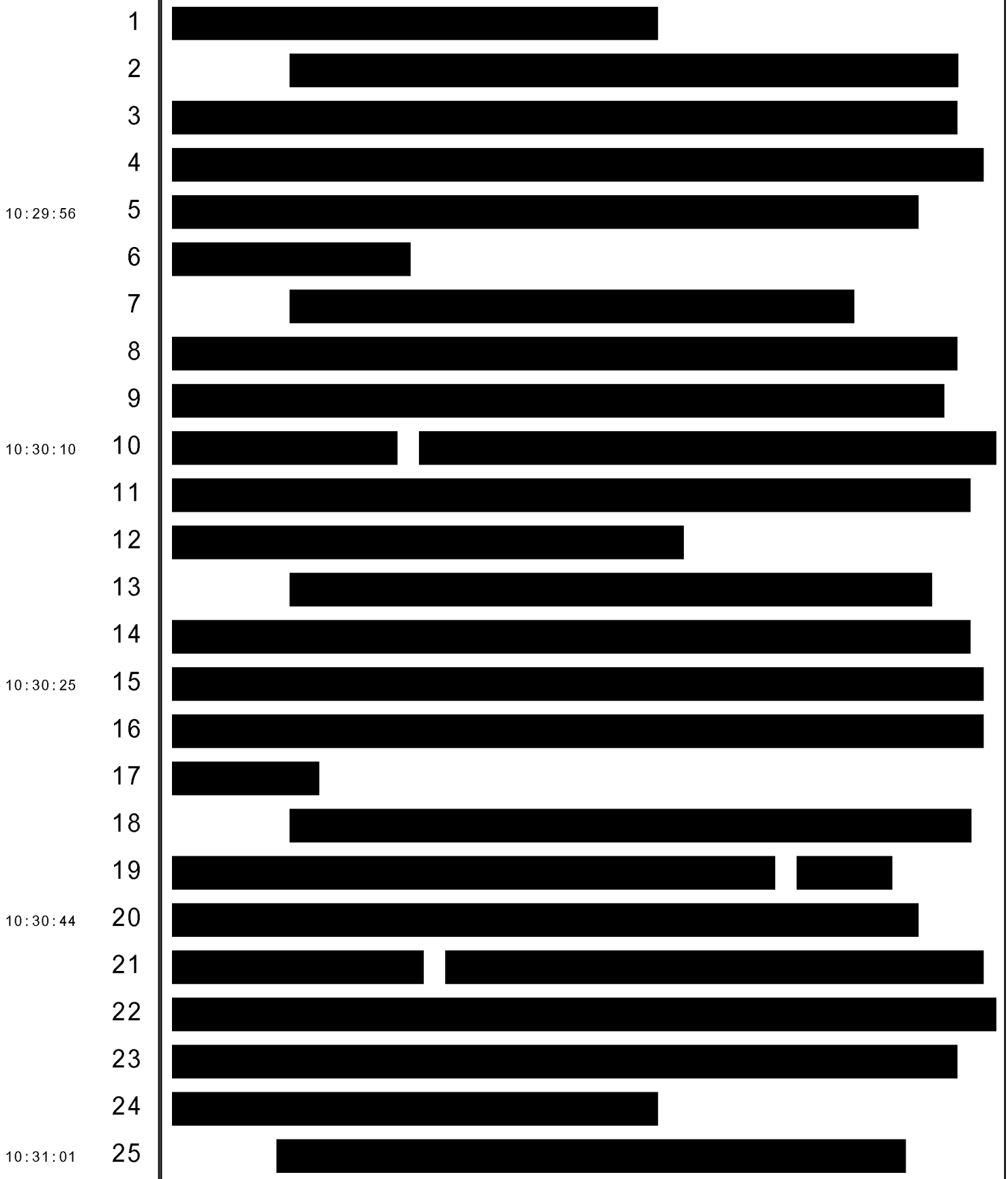
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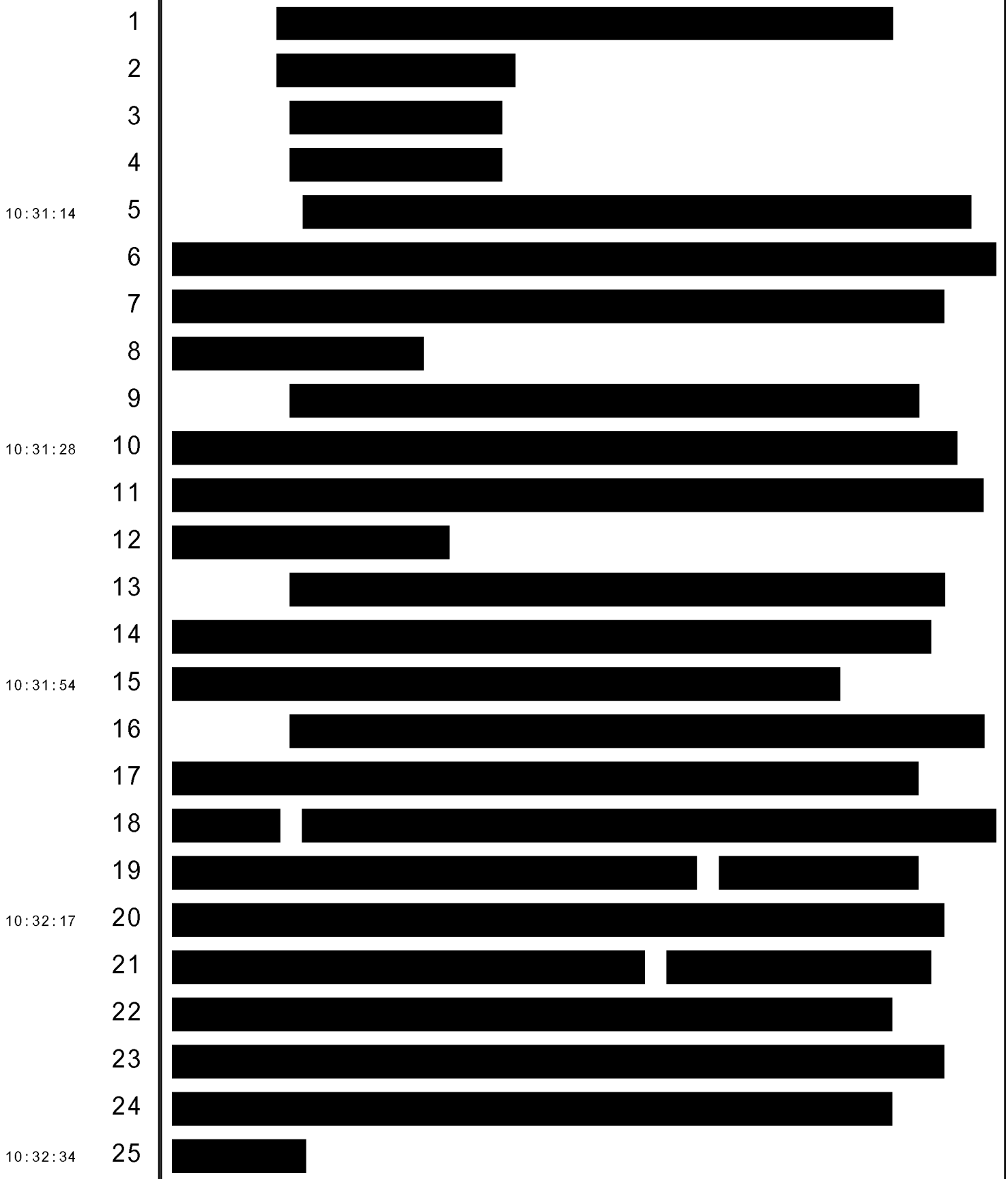
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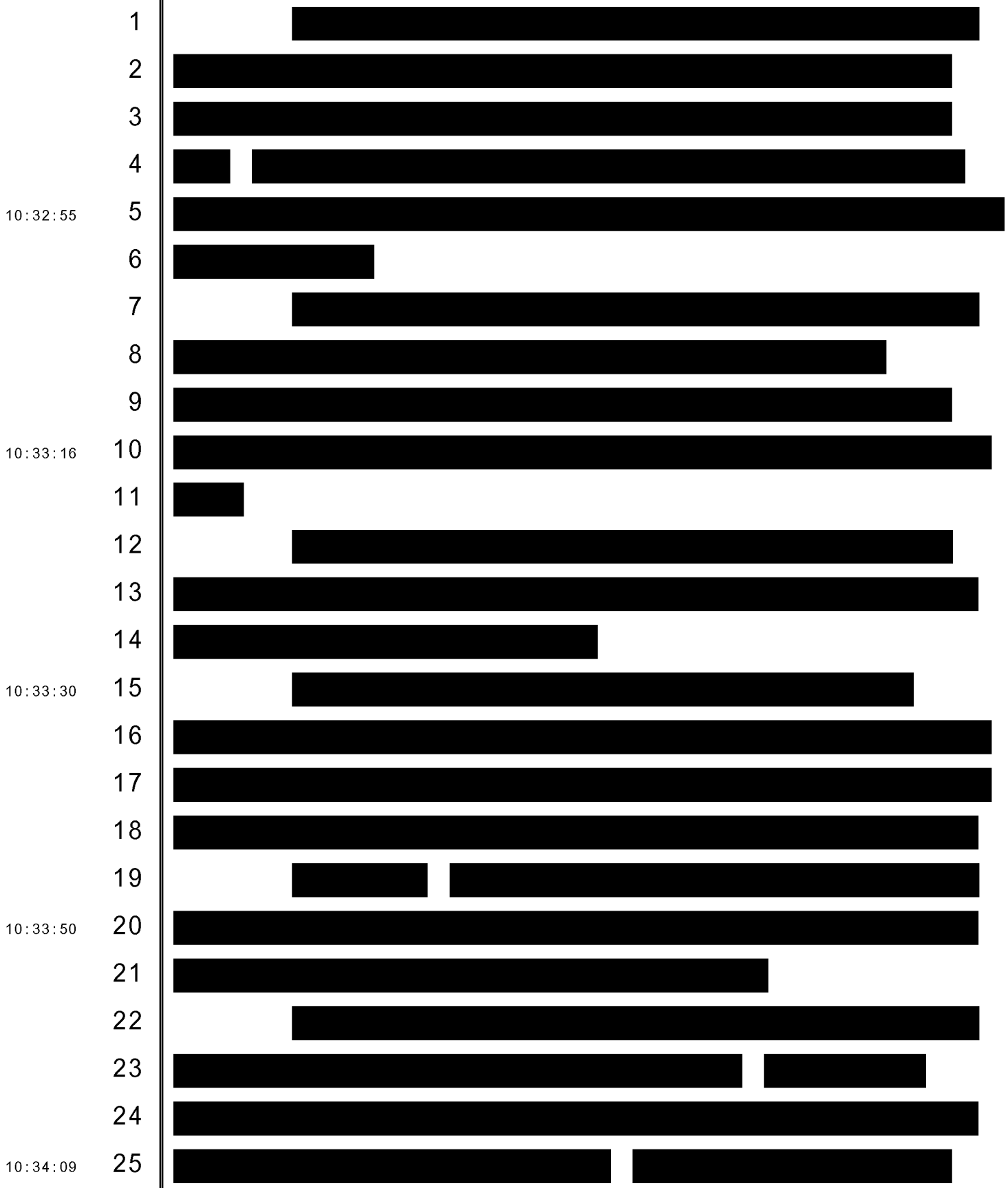
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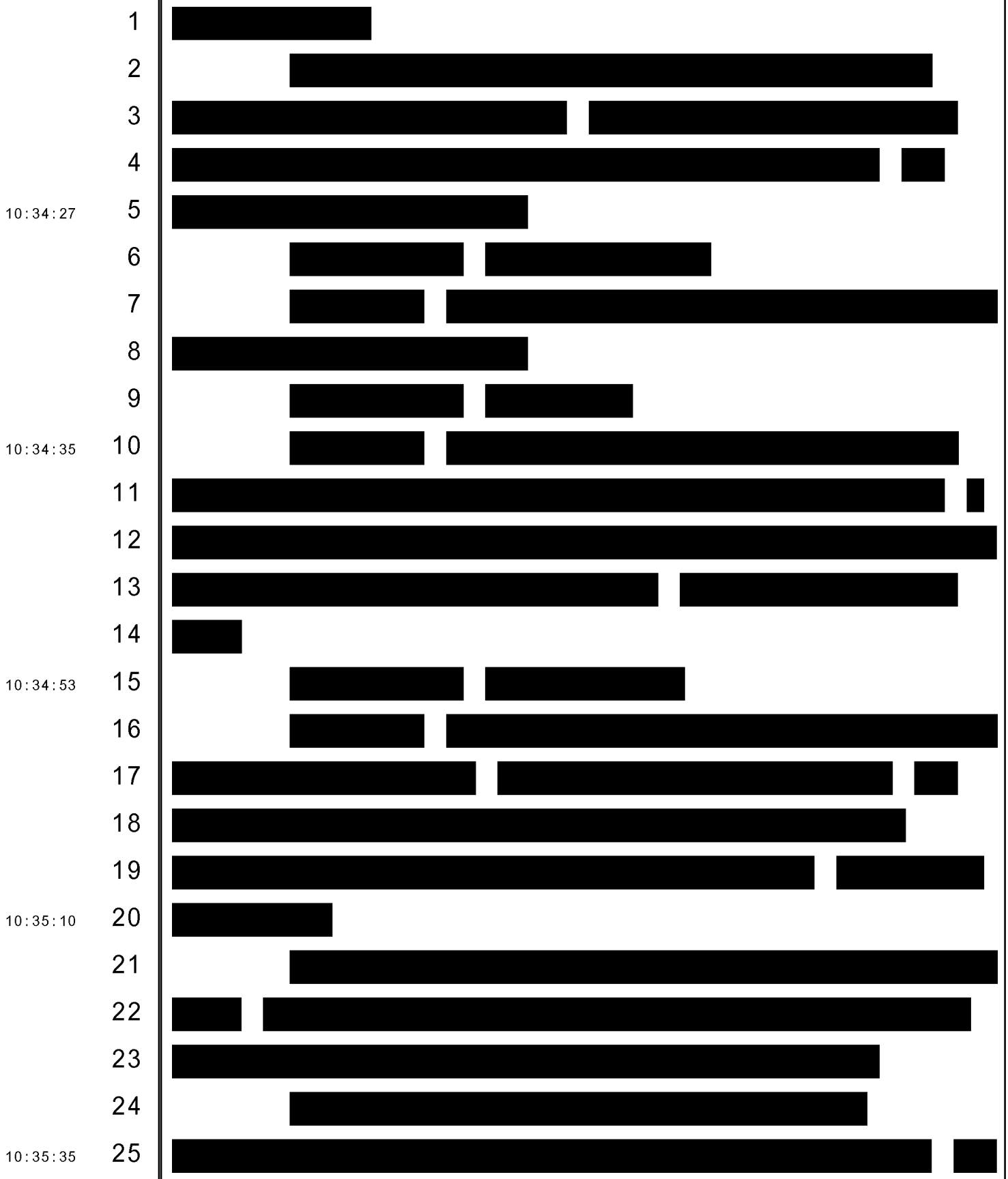
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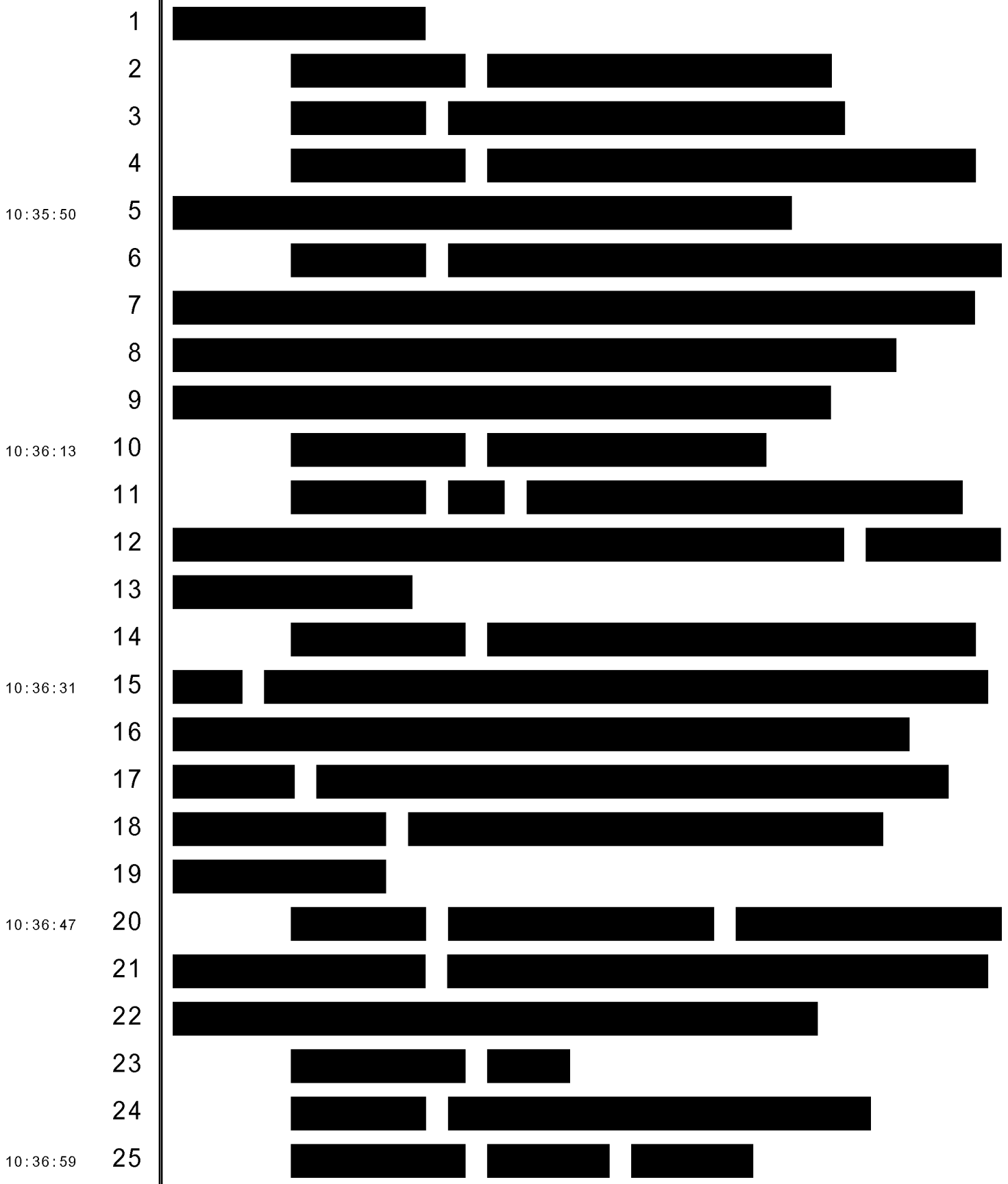
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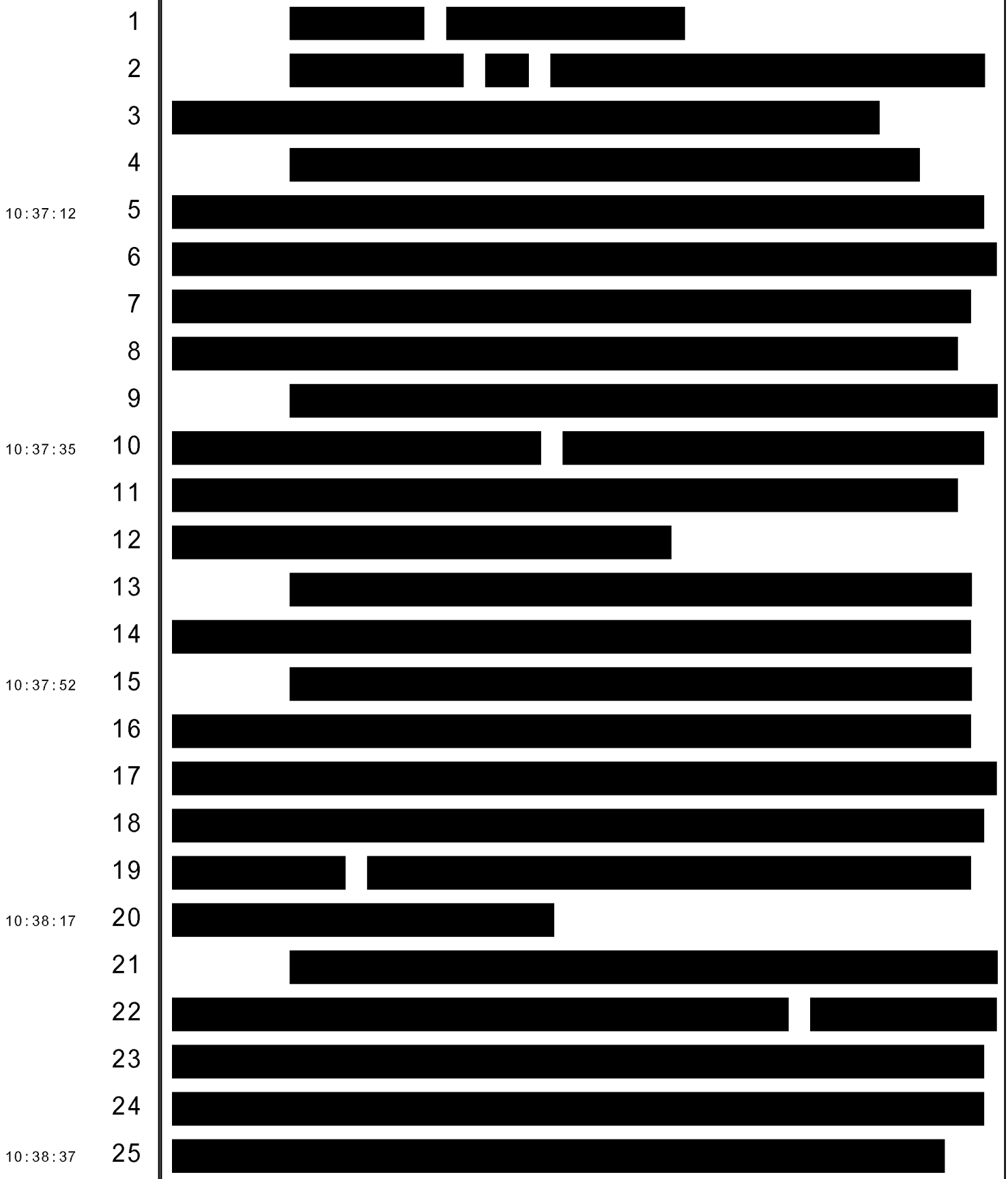
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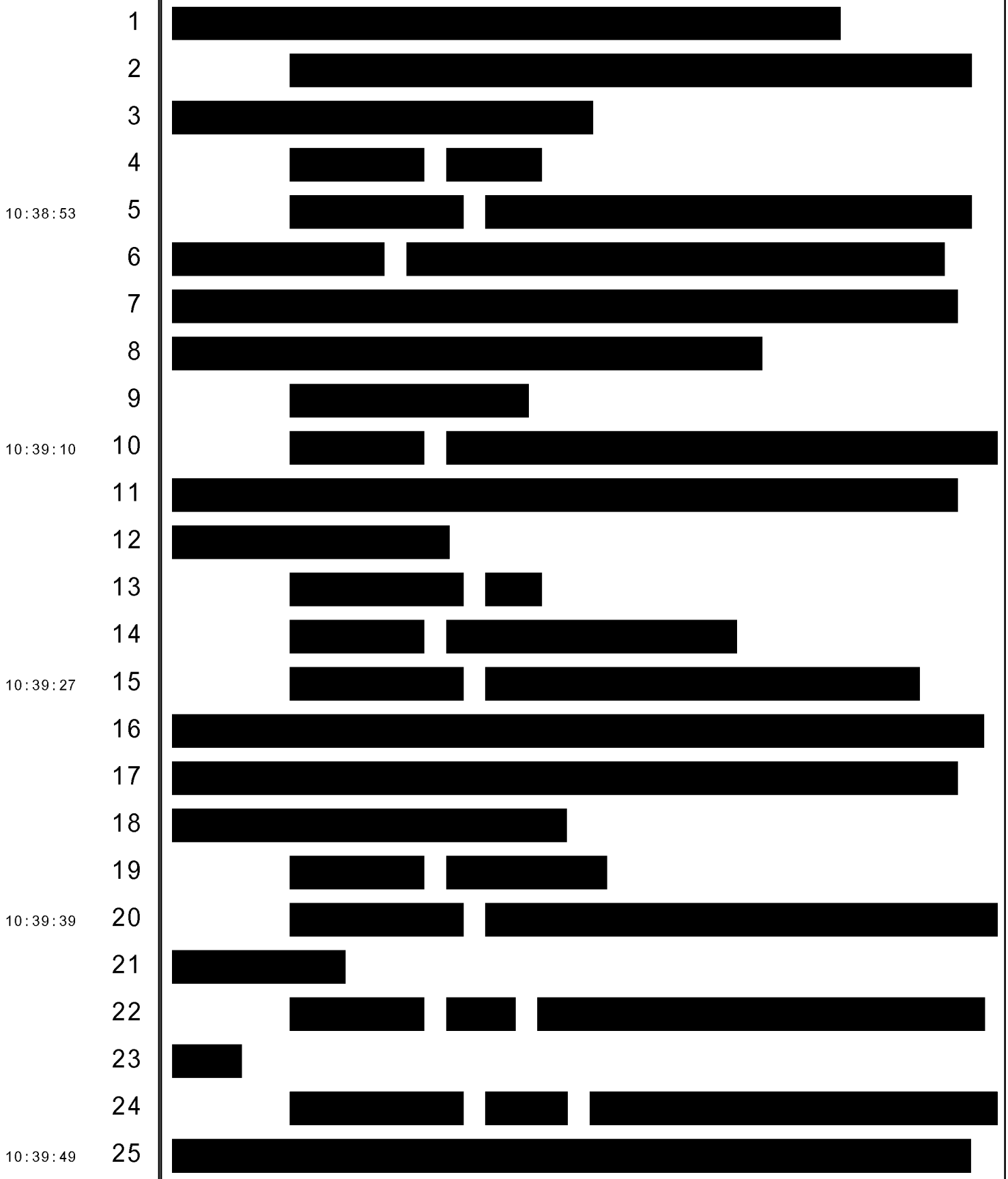
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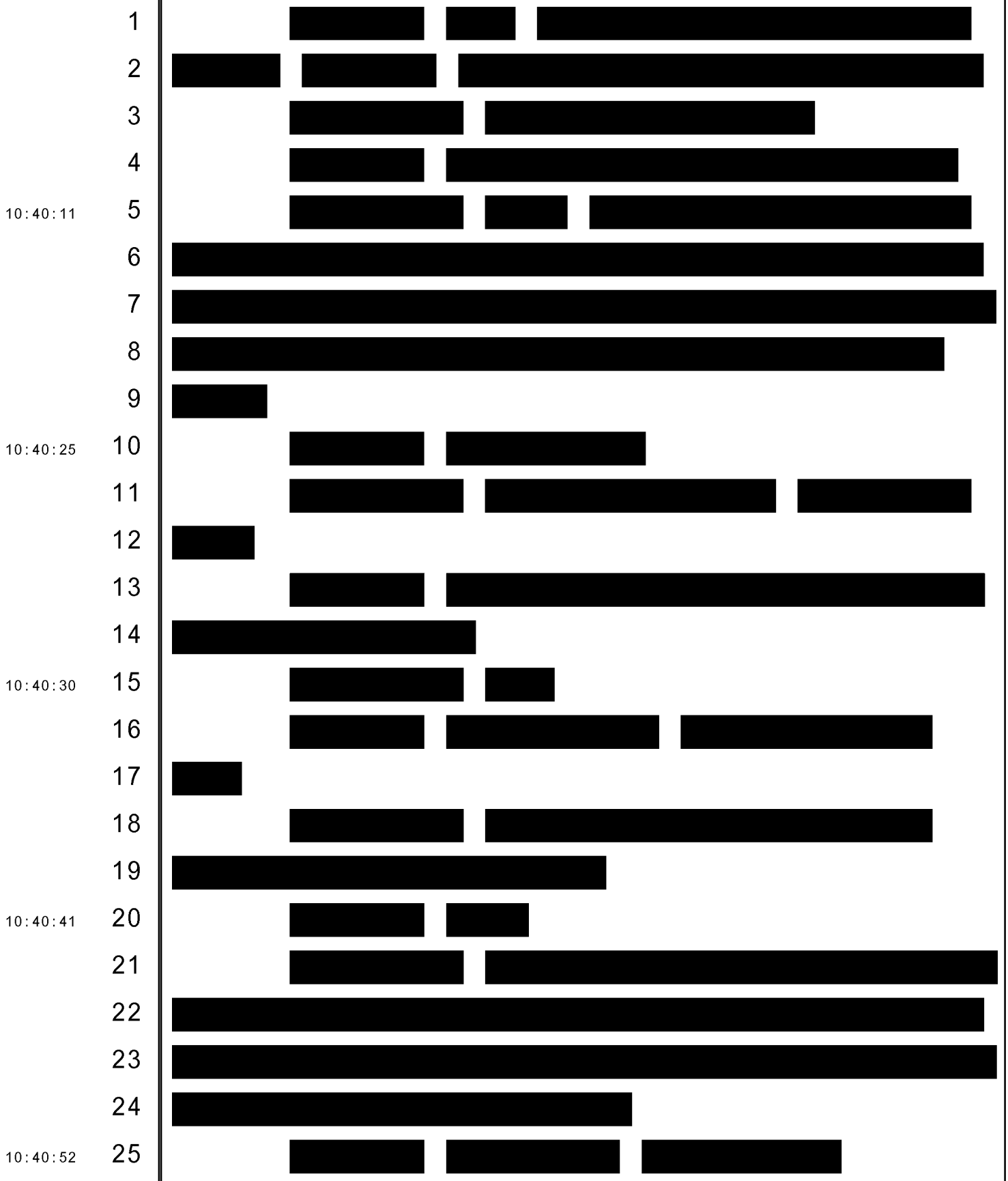
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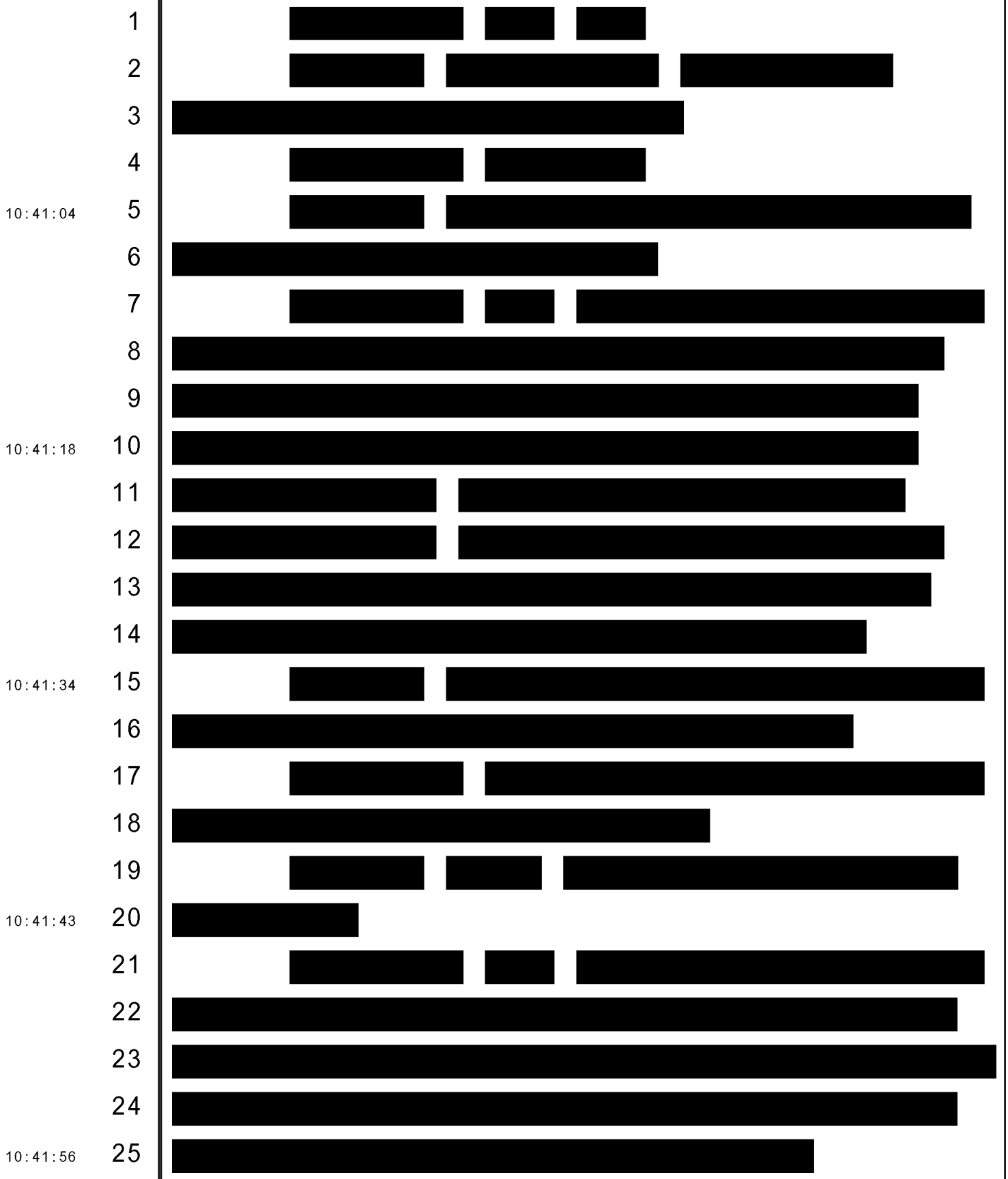
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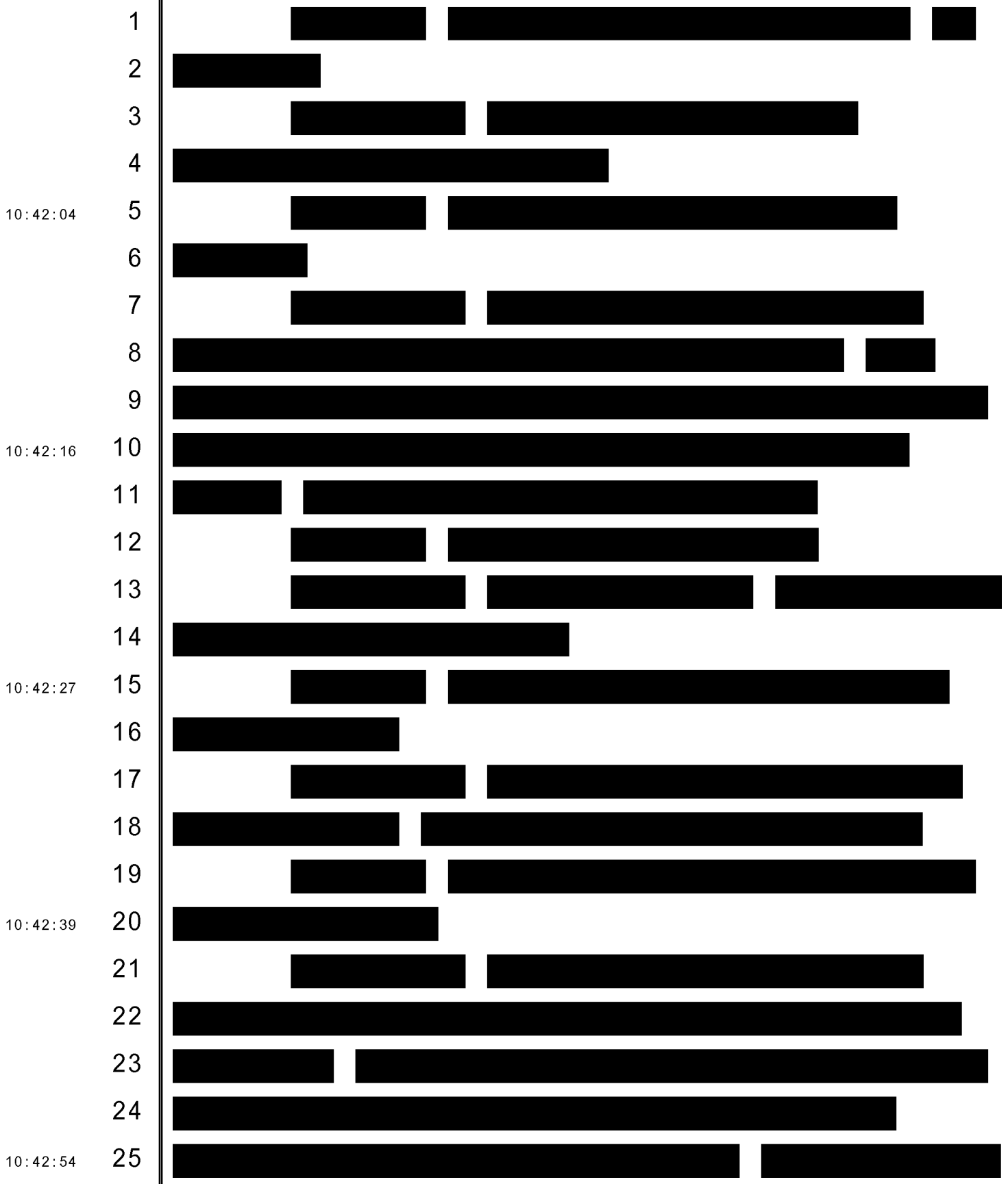
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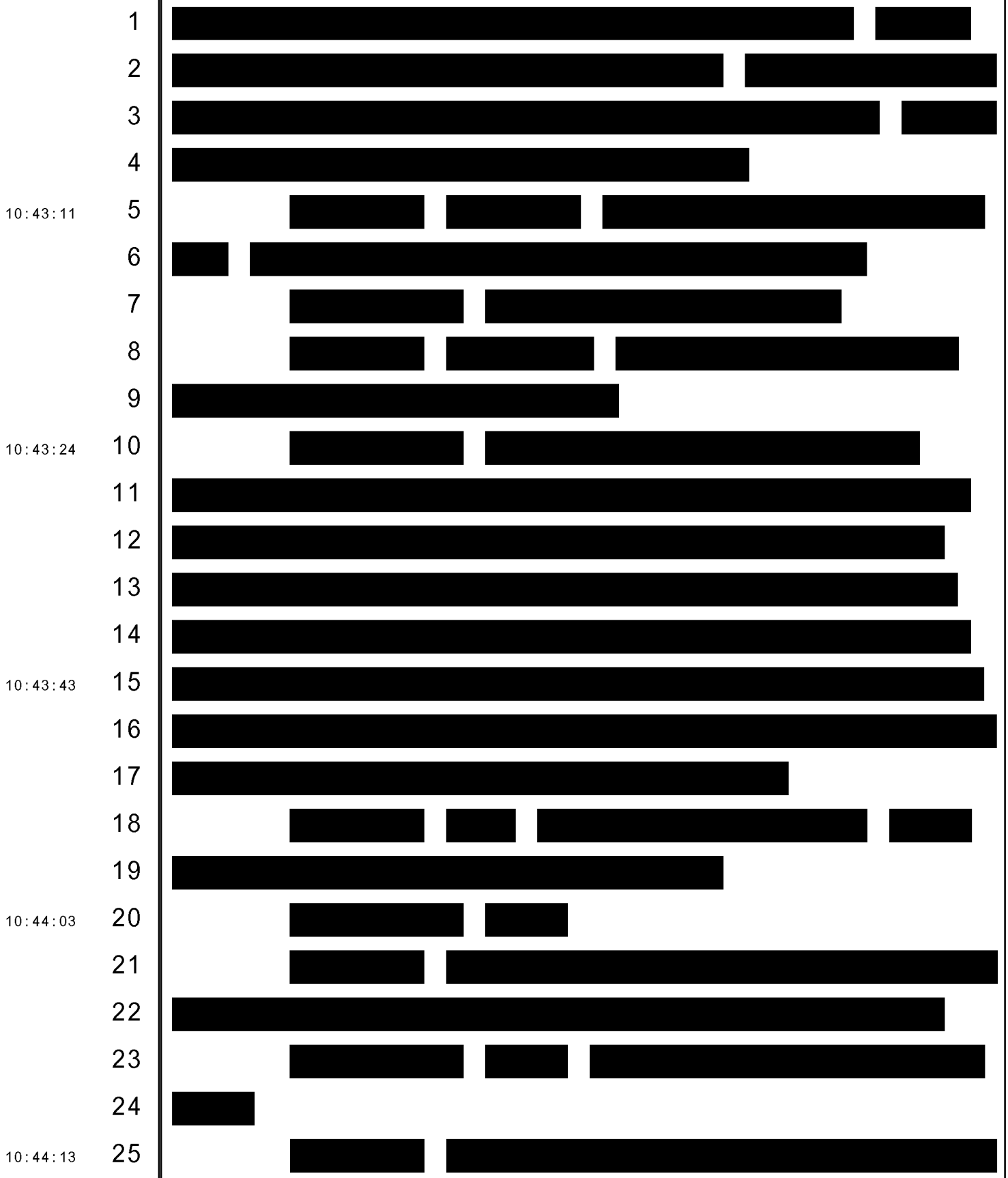
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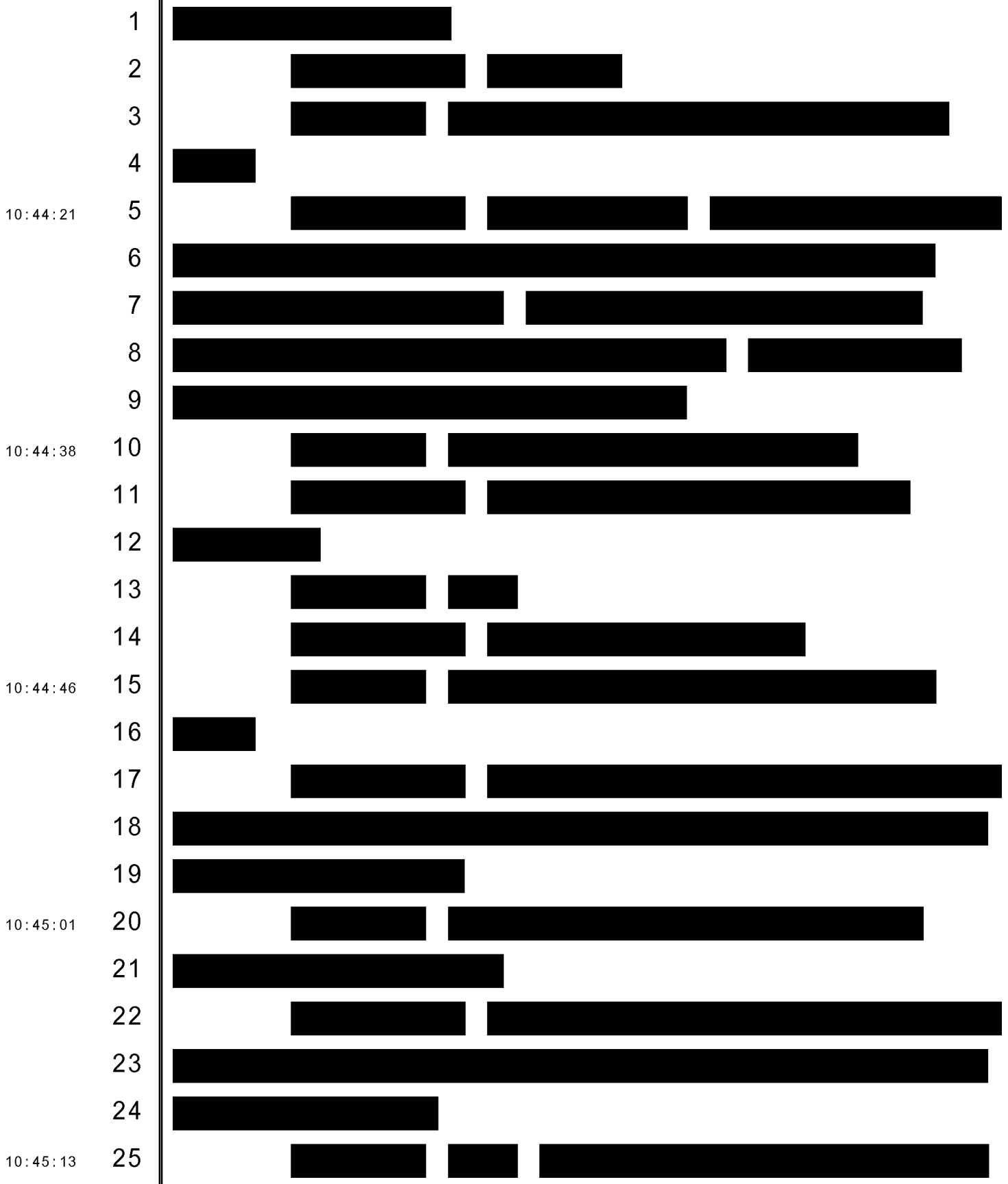
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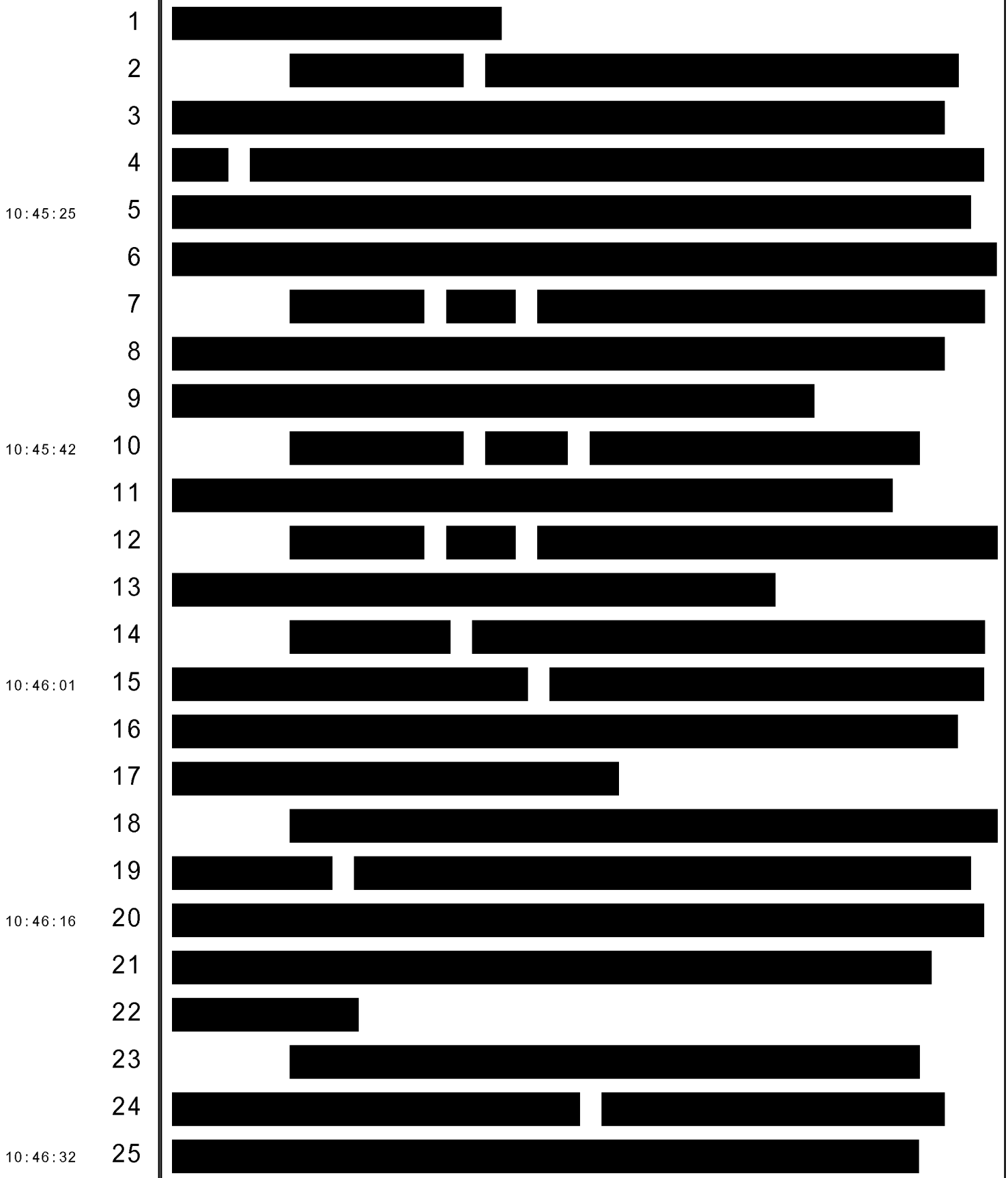
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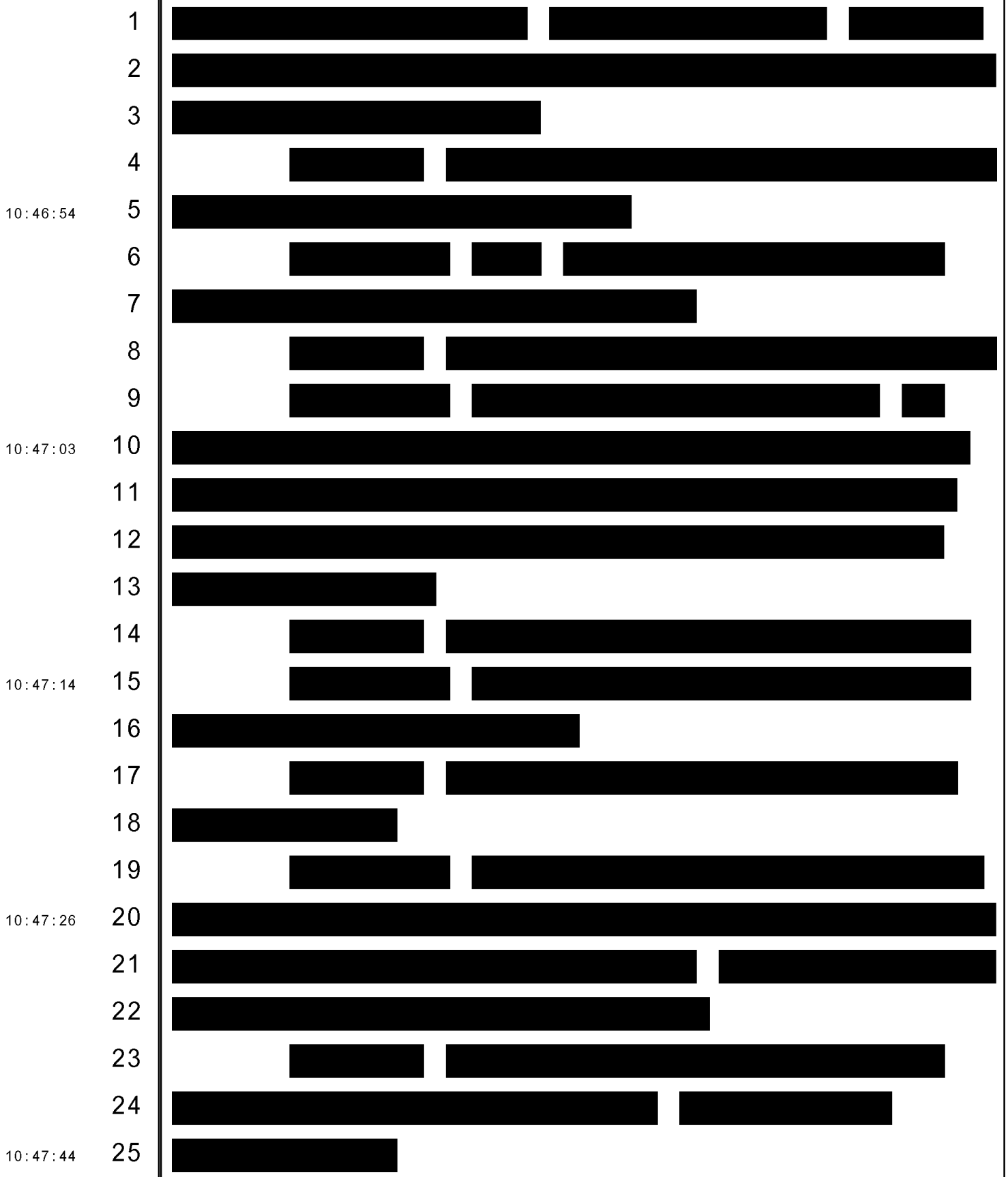
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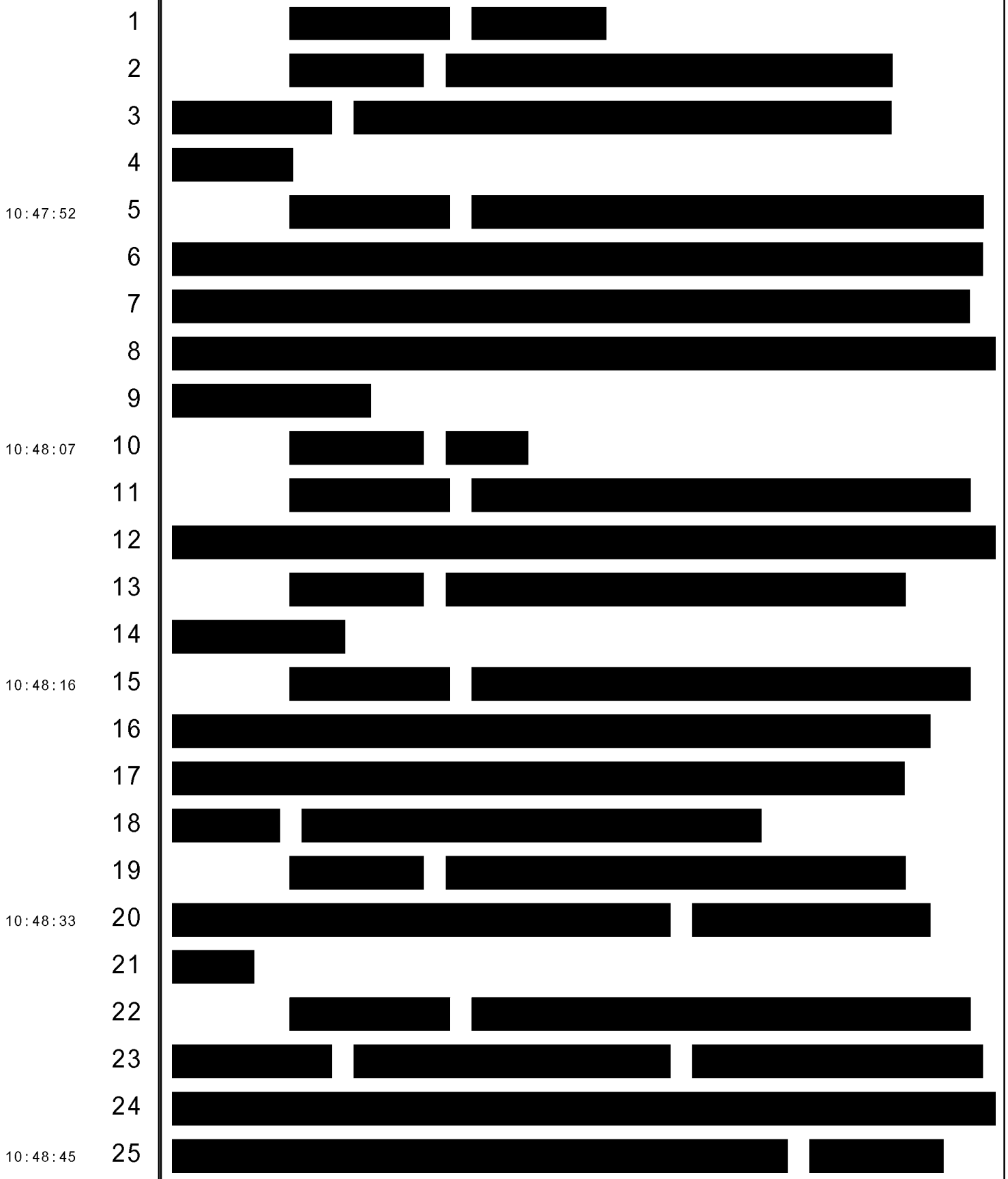
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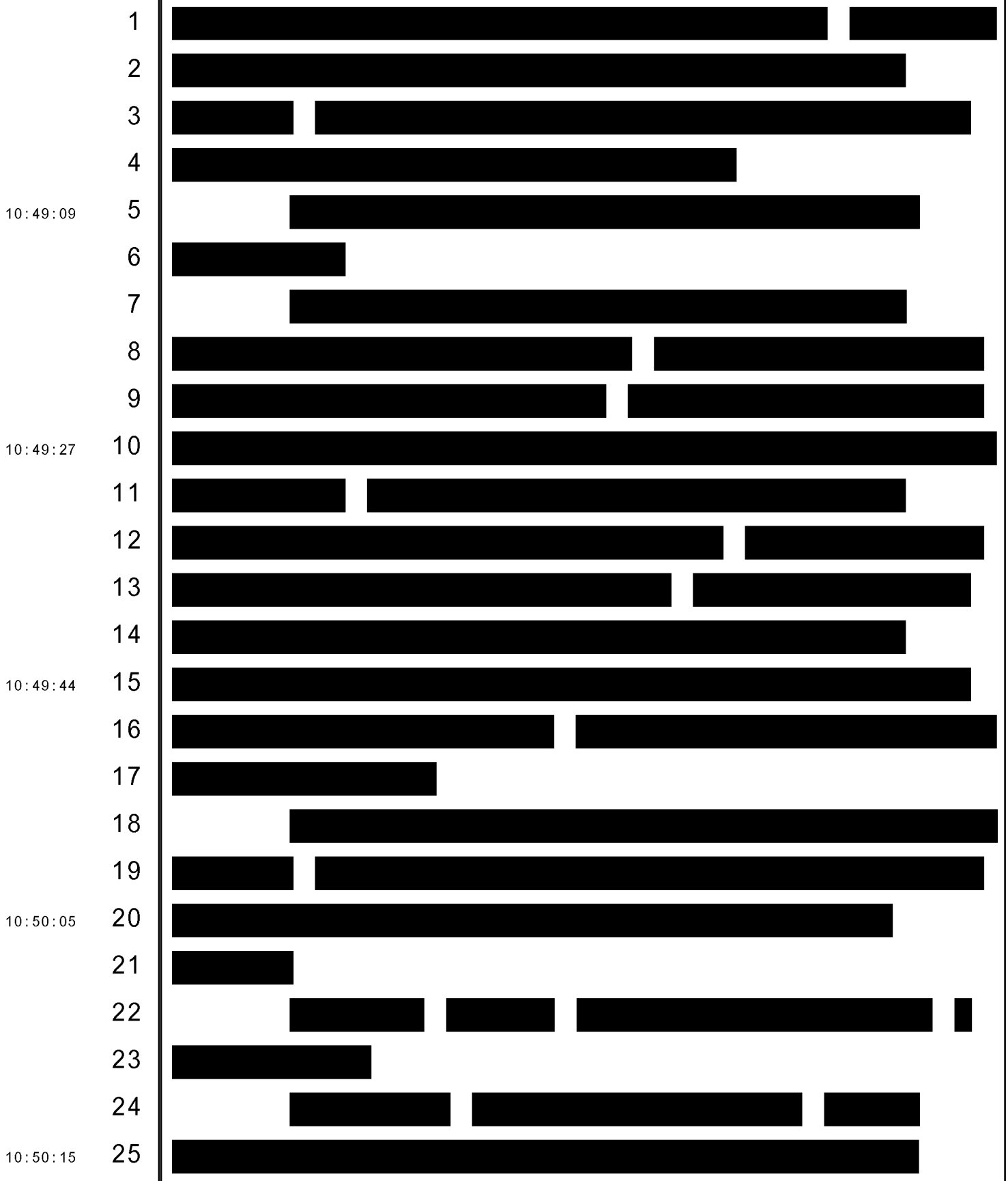
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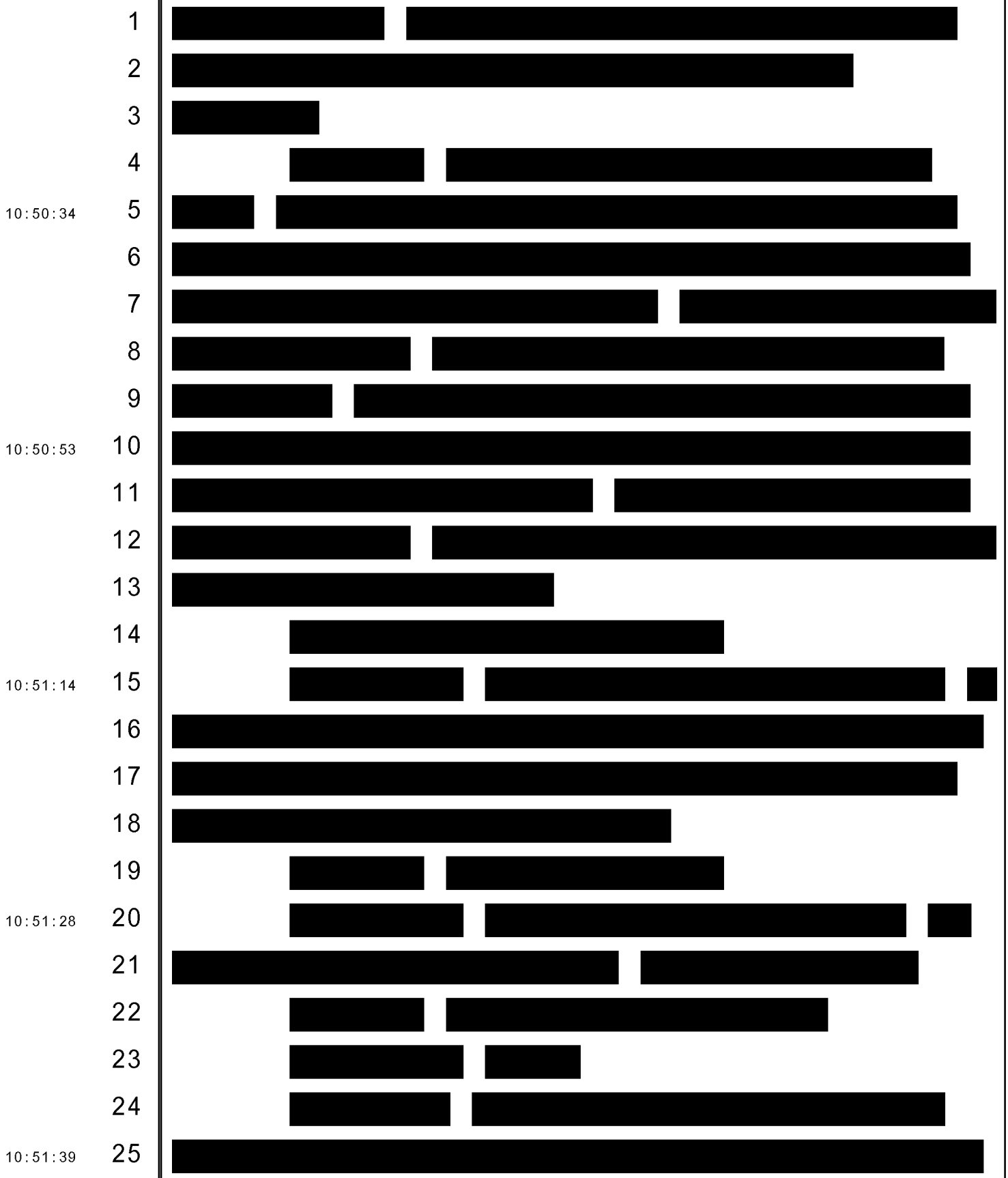
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(Recess.)

(The following proceedings were had out of the presence of the jury in open court:)

[redacted]

(The following proceedings were had in the presence of the jury in open court:)

THE COURT: All right. Thank you very much, ladies and gentlemen. Please be seated.

Step up here, please, doctor.

Please raise your right hand.

(Witness duly sworn.)

THE COURT: You may take the witness stand.

You may proceed, sir.

MR. DAVIS: Thank you, Your Honor.

ROBERT GIBBONS, DEFENDANT'S WITNESS, SWORN

DIRECT EXAMINATION

BY MR. DAVIS:

Q.

Ladies and gentlemen of the jury, counsel:

GlaxoSmithKline calls as its first witness Dr. Roberta Gibbons.

Dr. Gibbons is the Blum-Riese Professor of biostatistics at the University of Chicago. Dr. Gibbons conducts scientific research and analyses that assess whether a medication or other exposure causes side effects, including suicidal thoughts or behavior.

11:14:55

He gives lectures, teaches classes, presents papers to fellow statisticians, as well as to the medical community, particularly psychiatrists, and publishes scientific research in various scientific and medical journals on these issues and other scientific issues about public health.

11:15:11

He is a fellow of the American Statistical Association, a fellow of the International Statistical Institute, and a fellow of the Royal Statistical Society.

Dr. Gibbons obtained a Bachelor's Degree from the University of Denver in 1976 where he majored in chemistry and mathematics.

11:15:28

In 1981, he obtained a Ph.D. in statistics and psychometrics from the University of Chicago.

In 2010, after teaching for many years at the University of Illinois as professor of biostatistics, with joint appointments in departments of statistics and psychiatry, Dr. Gibbons joined the faculty of the University of Chicago where he continues to teach and conduct research as a professor of biostatistics.

11:15:43

He also continues to hold a position at the University

11:15:58

of Illinois as professor Emeritus of biostatistics.

In addition to his position as professor of biostatistics, Dr. Gibbons currently works at the University of Chicago as the Director of Center for Health Statistics, a Professor of Medicine, as Professor of Public Health Sciences, and as a Professor of Psychiatry. A major focus of Dr. Gibbons's research has been in the area of drug safety.

His statistical work and the methods he has developed have been applied thousands of times in the biological behavioral and social sciences.

Dr. Gibbons's worked in the subject of drug safety in general, and suicide in particular, dates back over 30 years.

After the leaving the University of Chicago as a graduate student in 1981, he joined the faculty of the University of Illinois at Chicago and had joint appointments at Rush Medical School here in Chicago at both the School of Medicine and the School of Public Health.

At Rush he worked with one of the leading researchers in suicide, Dr. Jan Fawcett. And while he worked with Dr. Fawcett they concentrated their research on identifying risk factors and causes for suicidal thoughts and behavior.

The Institute of Medicine of the National Academy of Sciences retained Dr. Gibbons to work on a national committee to assess suicide risk and prevention. As part of is work for that National Committee Dr. Gibbons used his expertise in

evaluating the scientific literature and data to assess both risk factors and causes for suicidal thoughts and behavior.

In 2010, he coauthored a report on these issues. The Institute of Medicine of the National Academy of Sciences are the leading advisers to the federal government on issues relating to our public health. It recruits leading scientists who participate --

11:17:41

MR. WISNER: Your Honor, I'm going to object. He's discussing facts about other institutes. This is supposed to be credentials. He has four more pages.

11:17:59

THE COURT: Just credentials, sir.

MR. DAVIS: Sure.

THE COURT: Just go back and give us his credentials.

MR. DAVIS: Sure.

11:18:04

Dr. Gibbons is one of the statisticians who works with the Institute of Health. And as part of his work for the Institute of Health Dr. Gibbons developed and designed the statistical methods for the analyses of suicidal events --

THE COURT: Sir, that will come out later. Give us his background.

11:18:17

MR. DAVIS: Yes, sir.

THE COURT: Where did he graduate and what are his credentials.

MR. DAVIS: Yes. And his --

11:18:22

THE COURT: Just that. Then you can bring these other

matters out as they may develop on direct.

MR. DAVIS: All right. Thank you.

Dr. Gibbons is a member of the American College of Neuropsychopharmacology that leading professional organizations that assesses the risk of psychiatric medications.

11:18:37

He has been an invited speaker of the American College of Neuropsychopharmacology, to speak at that organization's meetings about his research and his work in the area of antidepressants and whether they cause the risk of suicidal thoughts or behavior --

11:18:56

MR. WISNER: Your Honor, can we move this along? I mean, we're about to learn the name of his children and his dogs.

MR. DAVIS: I'm not sure this has to do with children and dogs, but I'll move it along.

11:19:03

Dr. Gibbons has authored and co-authored over 290 peer-reviewed publications which have appeared in various well-regarded journals in the field of medicine, psychiatry, public health and statistics. Those include the Journal of Clinical Psychiatry, the Journal of American Medical Association, the American Journal of Public Health, and the Journal of Statistics in Medicine, and the Journal of American Statistical Association.

11:19:20

In addition to authoring hundreds of scientific articles, Dr. Gibbons has also served in the editorial boards

11:19:32

of scientific journals that are charged with the responsibility of reviewing the work of other scientists to make sure it's worthy of publication.

Those journals include the American medical
11:19:47 Association for Psychiatry and the Health Services and Outcome Research Journal.

He has also published five leading textbooks on statistical methods, including how to assess and interpret scientific information in the areas of medicine and public
11:19:59 health.

His most recent book is called Statistical Methods For Drug Safety which was published in 2016, and is the only statistical textbook devoted exclusively to assessing drug safety.

11:20:11 This textbook analyzes how to interpret and assess scientific studies, including randomized placebo-controlled trials, metaanalyses, observational studies, and other scientific information so as to make determinations of whether --

11:20:25 MR. WISNER: Objection, Your Honor. He's talking about the content of a textbook.

MR. DAVIS: Just background information.

MR. WISNER: This is not credentials. This is just full-on argument.

11:20:33 THE COURT: That is argument, sir.

MR. DAVIS: I'm sorry.
THE COURT: That may come out later in your inquiry, I'll be surprised if it doesn't, but tell us now about his background credentials.
11:20:41 MR. DAVIS: Yes.
THE COURT: Where did he go to school and all that sort of thing --
MR. DAVIS: Yes, sir.
THE COURT: -- please.
11:20:47 MR. DAVIS: Over the course of his career, Dr. Gibbons has been honored many times by academic and professional organizations, and I will bring that out with the question.
THE COURT: I'm sure you will.
BY MR. DAVIS:
11:20:59 Q. Dr. Gibbons --
MR. WISNER: Your Honor, I object.
THE COURT: I haven't heard his credentials yet.
MR. DAVIS: Yes, Your Honor. He went to --
THE COURT: Tell me where --
11:21:08 MR. DAVIS: He went was in --
THE COURT: That's what I want to hear.
MR. DAVIS: He went to the University of Colorado in 1981. He joined the faculty.
THE COURT: Okay. Is he an M.D.?
11:21:10 MR. DAVIS: No, sir, he's not.

THE COURT: A Ph.D.?
MR. DAVIS: Yes, sir.
THE COURT: Okay. Any other degrees?
MR. DAVIS: Biostatistics.
11:21:23 THE COURT: Biostatistics, okay, fine.
MR. WISNER: Your Honor, at this time we move to strike this witness's testimony in its entirety. He is an admitted not an expert in suicide, as well as not being a medical doctor. He's being offered to offer testimony about a
11:21:39 drug he cannot prescribe to treat conditions he cannot treat.
THE COURT: Overruled, sir.
MR. DAVIS: Thank you, Your Honor.
BY MR. DAVIS:
Q. Dr. Gibbons, would you please introduce yourself to the
11:21:50 jury.
A. Hi. My name is Robert Gibbons and I'm a professor at the University of Chicago.
Q. Dr. Gibbons, what type of doctor are you?
A. I have a Ph.D. in statistics from the University of Chicago
11:22:01 which I received in 1981, and I have been a professor of biostatistics since that time.
Q. How long have you lived in the Chicago area?
A. 61 years.
Q. And what do you do for a living?
11:22:14 A. I'm a professor of biostatistics at the University of

Chicago. I'm the Blum-Riese Professor of Medicine and Biostatistics at the University of Chicago.

Q. Have you done research in the area of drug safety?

A. Extensively, yes.

11:22:27 Q. And have you done -- does your work include whether medications cause suicidal thoughts or behavior?

A. Yes, that is one of the fundamental areas of my work. Not only suicide, but a wide variety of adverse effects.

Q. Have you done any researcher and work in the area of mental

11:22:48 health and the prevention of suicide?

A. Yes. Mental health has always been a major focus of the application of my statistical work. I founded the mental health statistic section of the American Statistical Association, which now I understand has over 700 members.

11:23:05 Q. How long have you been involved in research and investigating causes of suicidal thoughts or behavior?

A. The early work with Jan Fawcett from Rush Medical School. Jan was the chairman of the Department of Psychiatry and absolutely delightful clinician and scientist. He was a part

11:23:29 of the National Institute of Mental Health, collaborative study of psychobiology of depression which established a large cohort of about 1,000 patients that were followed for over 27 years.

And so early on we were trying to determine if there was a way we could identify symptoms that people had that might

11:23:48 lead to suicidal thoughts and behavior, and that was really the

primary focus of our work at that time. This is probably in 1981 through 1985.

Q. Dr. Gibbons, have you worked at all with the National Institute of Mental Health?

11:24:03 A. Yes, we receive continuous funding from the National Institute of Mental Health of mental health for many, many years in a variety of areas related to statistical developments in the area of mental health in general. And also a lot of work and separate grants for looking at drug safety, what are 11:24:28 the methods by which we can determine whether or not there's a causal association between a particular exposure, like taking a drug, and an adverse event, like suicidal thoughts, behavior and completion.

Q. Have other federal government -- other federal agencies 11:24:45 reached out to you to retain your expertise in assessing scientific information and how to analyze studies to assess whether a medication or other exposure causes an outcome?

MR. WISNER: Objection; Compound and leading.

THE COURT: Yes, it has those.

11:25:04 MR. DAVIS: I'll rephrase.

THE COURT: Rephrase.

MR. DAVIS: Sure.

BY MR. DAVIS:

Q. Dr. Gibbons, have other federal agencies retained your your 11:25:10 services on the issues of analyzing scientific data?

A. Yes, they have.
Q. Have some of those agencies specifically retained you for purposes of assessing the risk and causes of suicide?
A. Yes, they have.
11:25:23 Q. Has that included the study and analysis of whether medications, such as selective serotonin reuptake inhibitors or SSRIs, cause suicidal thoughts or behavior?
A. Yes.
Q. Okay. Can you explain to the jury, please, who those
11:25:38 federal agencies are and what you did in connection with your work for them.
A. So, there have been a variety of experiences and participation I've had with different federal government agencies.
11:25:52 I was on the psychopathology advisory board of the FDA, Food and Drug Administration, and a member of the committee that led to the black box warning for antidepressants and suicide in children.
I was also brought in before that meeting to review
11:26:13 the statistical work that the FDA had done that was to be presented at that meeting of the psychopharm advisory board.
I've also been an adviser to now two secretaries of the Veterans Administration. I was a member of the Blue Ribbon panel about 5 years ago on the question of veteran suicide and
11:26:38 I'm an adviser to the brand new and delightful Secretary

Shulkin who is the new SECRETARY of Veterans Administration. I'm one of a small handful advisers to help with their number one priority, which is the reduction of veteran suicide, and we are developing methodologies to help achieve that very important goal.

Q. Thank you, Dr. Gibbons.

Could you move your mike a little bit closer to help us hear you. Or move closer to the mike. Thanks.

Dr. Gibbons, how many peer-reviewed scientific articles have you published?

A. Over 290 and 5 books.

Q. Have any of those dealt with the issue of antidepressants or SSRIs and suicidality?

A. A large number of publications in that specific area, probably over 30.

Q. Now, in terms of recognition for your work as someone who's done research either in biostatistics or on the issue of assessing suicidality, have you received any awards?

A. Yes.

Q. What awards have any received?

A. I was given the -- well, for one, I was elected to the membership of the National Academy of Medicine of the National Academy of Sciences for contributions to the statistical underpinnings of drug safety.

I was given the American Statistical Association's

Outstanding Statistical Application Award for the explication of the relationship of antidepressants and suicide.

I've been given the Harvard award for contributions to Psychiatric Epidemiology and Biostatistics.

11:28:47 The American Public Health Association's Rema Lapouse award for contributions to psychiatric epidemiology.

The health policy statistics section of the American Statistical Association for work in the measurement of mental health constructs, including suicidality.

11:29:08 Q. Dr. Gibbons, have you ever been invited to come and speak at a group of, you know, professional organizations that focus on psychiatric medications?

A. Yes.

Q. And what groups have invited you to come and speak?

11:29:23 A. I -- I gave a lecture on the statistical methods of drug safety invited by the Department of Statistics at Harvard University.

I was the keynote speaker at the last two World Congresses of Suicide Research.

11:29:42 And there have been several others at different universities.

I, a week ago, gave the grand rounds at the University of Colorado on the statistical methods for drug safety.

Q. Are you a member of the American College of

11:29:58 neuropsychiatrically?

A. Yes, I am.
Q. Have you been invited by the American College of Neuropsychopharmacology to come and speak on the issues of antidepressants and whether or not they cause suicidal thoughts or behavior?
11:30:10
A. Yes; several times over the last decade.
Q. And just for the jury's benefit, what is the American College of Neuropsychopharmacology?
A. It's a very long title, but it is the leading psychiatric organization involved in the research and practice of psychiatry and biological underpinnings of mental health disorders.
11:30:26
Q. Dr. Gibbons, what were you asked to do for this particular case?
A. I was asked to review the literature on the relationship between antidepressants in general, and suicidal thoughts, behavior and completion, and Paroxetine in particular, and to determine whether or not there's a causal association between taking Paroxetine and the development of suicidal events, suicidal thoughts, behaviors and completion.
11:30:43
11:31:13
Q. And for the purpose of this case, were you asked to specifically focus your attention and opinions on whether or not Paxil or Paroxetine cause suicidal thoughts or behavior in adult patients?
A. Yes; that's correct.
11:31:27

Q. What have you done to prepare to give those opinions in court today?
A. I've reviewed the entire literature. The scientific peer-reviewed published literature. I've reviewed the FDA
11:31:41 reports on their large scale research synthesis of these data. I've reviewed expert reports in this case of plaintiff experts. And just the proceedings of -- of this case -- of this --
THE COURT: You got to keep your voice up, Doctor.
THE WITNESS: I'm sorry.
11:32:03 BY MR. DAVIS:
Q. How much time did you spend working on this case in order to prepare to deliver your opinions that you would give in the case?
A. Someplace in the order of 100 to 150 hours.
11:32:16 Q. And do you get paid for your time?
A. I do.
Q. How much do you charge for your time?
A. $850 an hour for the preparation of this work and $1,000 an hour for deposition and courtroom testimony.
11:32:29 Q. What accounts for the difference between the 850 for the review and the $1,000 for testimony?
A. During testimony and deposition I -- I -- my schedule is -- has to be kept completely open for the schedules of the court. And also, I have to be very careful not to think about lots of
11:32:48 other things so that I can really focus on the issues related

to this particular trial.
Q. Have you been an expert in other lawsuits where you are asked to assess the scientific information available on whether a medication or an exposure causes a medical condition or
11:33:04 outcome?
A. Yes.
Q. And in cases not involving Paroxetine or Paxil, have you worked as an expert where there's an issue about whether the medication caused or increased the risk of a medical condition
11:33:18 or suicidal thoughts or behavior?
A. Yes.
Q. And who retained you in those cases?
A. I've been retained by the U.S. Department of Justice, I've been retained by Wyeth Pharmaceuticals, Pfizer Pharmaceuticals;
11:33:39 there are a few others.
Q. Have you testified at a trial?
A. Yes, I have.
Q. What trial was that?
A. This was the Giles trial. This was a trial about the drug
11:33:52 Effexor, the Wyeth drug. This was a suicide and antidepressant trial similar to this one.
Q. Other than this case, have you been retained by GlaxoSmithKline to work on any other cases?
A. Yes; there's a case in the United Kingdom, in London, that
11:34:08 I have participated in related to a potential adverse effect of

Paroxetine.
Q. Is that particular proceeding involve suicidal thoughts or behavior?
A. No, not directly.
11:34:22 Q. Okay. And what percentage of your time do you spend working as an expert in litigation?
A. Maybe 10 percent of my time.
Q. So what do you do with the other 90 percent of your time on a day-to-day basis?
11:34:34 A. I teach students, I do research, I run a center at the University of Chicago and play tennis.
Q. Based on your own research and your review of research by others, have you reached opinions to a reasonable degree of scientific certainty regarding whether Paroxetine or Paxil use
11:34:57 causes suicidal thoughts or behavior in adult patients?
A. Yes.
Q. For each of the opinions that you're going to offer today, do you hold them to a reasonable degree of scientific certainty?
11:35:08 A. Yes, I do.
Q. Did you and I work on a collection of slides that would help the jury understand your opinions?
A. We did, yes.
Q. And do you believe the use of those slides would be helpful
11:35:17 to the jury in understanding the scientific evidence on whether

Paroxetine or other SSRIs cause suicidal thoughts or behavior in adult patients?

A. I do.

MR. DAVIS: Your Honor, permission --

11:35:27 THE COURT: Why don't you ask the doctor what his opinion is first so we know what you're trying to support.

MR. DAVIS: Sure.

BY MR. DAVIS:

Q. Dr. Gibbons, if you could, please, for the jury's benefit,

11:35:38 could you summarize your opinions.

A. My opinion is is that SSRIs in general, and Paroxetine in particular, do not increase the risk of suicidal thoughts or behavior or completion. If anything, they decrease the risk of these events.

11:35:53 Q. Dr. Gibbons, the jury has heard evidence -- let me back up.

The jury has been told that the scientific data actually shows that Paroxetine causes suicidal thoughts or behavior or completed suicide. Is that a fair assessment of where we are today on the science?

11:36:10 A. That's not fair at all.

Q. Tell us, in your own view, why that's not fair, why that is not a fair assessment of evidence with respect to Paroxetine and other SSRIs in adult patients.

A. There's a tremendous amount of data now available on the

11:36:26 question of whether or not antidepressants in general, SSRIs in

particular, and Paroxetine in particular, increase risk of suicidal thinking, behavior or completion. These include numerous, hundreds and hundreds of randomized controlled trials that have the benefit of randomization to rule out confounding by other factors that might lead one person to seek treatment and another not.

Those data are very, very clear. In particular, the FDA synthesis of 372 randomized controlled trials in 100,000 patients, that these drugs either decrease the risk of the combination of their primary endpoint of suicidal thinking and behavior or have no effect overall on suicidal behavior, neither increase it or decrease it in the adult population.

As we age, as we get to the population of over 65, there are benefits, significant reductions in not only suicidal thoughts but also suicidal behavior. These are the findings of the US FDA.

Q. Dr. Gibbons, does that hold true also specifically with respect to Paroxetine?

A. Yes, it does.

Q. Now, what types of studies have you relied upon for purposes of forming the opinions that you just gave?

A. So the importance of randomized controlled trials is that they eliminate bias, bias on things that we can see and measure, and also bias on some things that we can't because of randomization.

You can manage with the advances in molecular genetics that we've all seen and read about, that there may be genes that would influence whether or not someone would have suicidal thoughts or behavior.

11:38:28 The advantage of randomized controlled trials is even if there are genes we can't measure, we will balance those people who receive placebo or sugar pill or an active medication like Paroxetine in terms of all of those observed and unobserved findings or potential confounders. So those

11:38:49 data are terribly important for deriving an inference about whether or not there is any relationship between antidepressants and suicide.

Now, the people who get into randomized controlled trials may not be totally representative of the people who

11:39:05 ultimately take the drugs, and the amount of time that these studies go on for may not be representative to the experiences of individuals in the real world. For that reason, it's extremely important to also not only look at randomized controlled trials but to well-controlled observational studies

11:39:25 conducted in hundreds of thousands, and in some cases millions of people, for the ultimate end users of these products to see whether or not the findings from a randomized controlled trial do, in fact, generalize to the real world of real people who take these drugs.

11:39:41 Those are the two main streams of data that I have

focused my attention, not only in the context of this case but in my academic work.

Q. Why is it that we need that specific type of scientific evidence to figure out whether or not a medication such as Paroxetine causes suicidal thoughts or behavior?

11:39:55

MR. WISNER: Objection; vague as to what scientific evidence he's referring to. He's testified about two of them. I don't know which one he's talking about.

MR. DAVIS: I believe it's the randomized control trials he talked about and the observational studies that he mentioned, Your Honor.

11:40:10

THE COURT: All right. You may proceed.

MR. DAVIS: Thank you.

BY THE WITNESS:

A. With respect to the randomized controlled trials, they are the gold standard because they eliminate the potential for bias.

11:40:15

We can imagine that patients who are sicker are more likely to be treated with the more novel treatments, the newer kinds of treatments. And that sickness may be confounded with adverse events they might experience, including suicide.

11:40:28

All of that potential bias is eliminated in randomized controlled trials, that's why they're so important.

But equally important is the idea that what we observe in a well controlled laboratory setting actually generalizes to

11:40:45

the population of potential users of these drugs, and that's why the observational studies are important.

The observational studies are also much larger. It's easy for us to obtain medical claims data on the experiences of
11:41:05 millions of Americans to be able to identify whether or not even rare events like suicide attempts and even suicide actually are related to exposures to different kinds of drugs, antidepressants, antiepileptic drugs, different kinds of drugs.

Q. Dr. Gibbons, you mentioned randomization. Later on, are we
11:41:29 going to talk about randomization and how that process works to try to get to the right answer in terms of how studies need to be done?

A. Yes.

Q. All right. So we're going to park that to the side briefly
11:41:39 and we'll come back to it.

The jury has heard a lot about two terms, one of those terms is "association," and the other term is "causation." Are they the same?

A. Oh, absolutely not.

11:41:51 Q. Have you and I prepared a slide that helps explain the difference between association and causation?

A. Yes, we have.

MR. DAVIS: Your Honor, permission to publish slide 5, which is DX7035E.

11:42:05 MR. WISNER: I'd like a copy of these things before he

tries to publish them to the jury.

MR. DAVIS: I'm getting them, Your Honor.

MR. WISNER: Don't ask to publish before you have shown them to me.

11:42:12 (Binder tendered).

MR. WISNER: All of these (indicating).

MR. DAVIS: Your Honor, do you need a set?

Permission to approach.

(Binder tendered to the Court.)

11:42:37 MR. WISNER: Your Honor, it appears to be over a hundred pages here.

THE COURT: Why haven't these been shown to counsel before?

MR. DAVIS: Your Honor, I gave him a copy. He's got a

11:42:48 copy.

THE COURT: He has a a copy now, but it's 100 pages. Why didn't you show them to him before?

MR. DAVIS: I apologize.

THE COURT: I don't know if that's going to take care

11:42:58 of it.

(Brief pause).

THE COURT: You want to go through these first, Mr. Wisner?

MR. DAVIS: It's the fifth one. It's the DX7035D.

11:43:12 THE COURT: All right. Well, start with that one,

then.

MR. WISNER: No objection to that one, Your Honor.

MR. DAVIS: Thank you.

(Exhibit published to the jury.)

11:43:23 BY MR. DAVIS:

Q. Dr. Gibbons, using this slide can you help us understand the difference between association and causation.

A. Of course. So this is a very simple toy example, but it illustrates the point. People who wear helmets have a greater

11:43:40 incident of broken bones. It's not because wearing the helmet is causing the broken bones, it's because the people who wear helmets engage in risky behaviors like motocross racing or skiing, aerial skiing, or snow boarding. And people who engage in those riskier sports or behaviors have an increased risk of

11:44:11 broken bones.

So the association between wearing a helmet and broken bones is not a causal association, it's mediated by the participation in risky behaviors that increases the likelihood of having broken bones. So it's an indirect effect rather than

11:44:27 a direct effect.

The causal effect is a direct effect. Putting on the helmet somehow increases the likelihood of a broken bone not because their -- regardless of the behavior. So we know that putting on a helmet is not increasing broken bones.

11:44:50 Q. Did you and I also work on a slide to show how the

scientific community assesses whether a medication causes an adverse effect or a medical condtion such as suicidal thoughts or behavior?

A. Yes, we did.

11:45:02 MR. DAVIS: Permission to publish DX7035E, Your Honor, which is the next slide, slide 6.

THE COURT: All right.

MR. WISNER: No objection, Your Honor.

(Exhibit published to the jury.)

11:45:16 BY MR. DAVIS:

Q. Dr. Gibbons, can you help us understand what this slide is showing in terms of how one goes about from a scientific standpoint to determine causation.

A. So we begin with randomized controlled trials. They're the 11:45:31 gold standard of scientific inference for drawing causation.

And I've mentioned already the reason they work so well is that we balance all of the potential biases and confounders both that are observable and that are unobservable or unmeasured.

11:45:52 We next look to see whether or not the results from a randomized controlled trial replicate across a large number of randomized controlled trials. And we do that with different approaches to research synthesis sometimes called meta-analysis. It's the combining of evidence from multiple 11:46:13 studies that have all studied the same phenomenon in a similar

way.

Comparison of placebo to Paroxetine in terms of suicidal ideation and/or behavior across multiple studies to see are we getting a consistent effect, how much variability is there in that effect, and overall, what is the magnitude of that effect.

11:46:30

The magnitude of that effect is the third point, that is the strength of the association. Is the increase in risk a very tiny increase in risk that may be statistically significant because we have such large sample sizes or is there an appreciable risk, are we seeing a doubling of the risk or a tripling of the risk. How strong is the association between the exposure, the taking of a medication and the outcome of interest that we're investigating.

11:46:46

Fourth, what I mentioned before about the importance of observational studies, how well do those randomized controlled trials under very precise laboratory conditions generalize to the population of real people who take these medications, of people in the real world who take them for short periods of times or very long periods of time. Do we see the same kind of findings out in the real world environment.

11:47:03

11:47:22

These are less rigorous data, because there not randomized. So, it may be that sicker patients are actually receiving the medication more frequently than less sick patients, but we still should be able to see that. We see the

11:47:39

similar effect in the real world.

And then finally, it's important to also show that there is a dose response relationship. The more you take of a drug, or at the higher concentration, the greater the effect of that drug on the outcome of interest.

Q. Now, when you have a medical condition such as anxiety or depression, and also -- which also cause suicidal thoughts or behavior --

MR. WISNER: Objection; move to strike. Mr. Davis nor this man on the stand is a medical doctor and can testify about this.

MR. DAVIS: Your Honor, I think this has already been addressed.

MR. WISNER: He cannot say. He's not a doctor, nor is this guy (indicating).

THE COURT: Sustained.

BY MR. DAVIS:

Q. Let me back up.

Dr. Gibbons, are you familiar with the -- with both depression and anxiety and what are risk factors for depression and anxiety?

A. Risk factors for depression and anxiety, yes.

Q. Yes. And have you researched and investigated what -- what risk -- whether depression and anxiety or risk factors for suicidal thoughts or behavior?

A. Yes.
Q. Have you -- and as part of your work and research, are anxiety or depression risk factors for suicidal thoughts or behavior?
11:48:55 MR. WISNER: Objection; lacks foundation and proper opinion. If I may voir dire the witness, Your Honor, I believe I can lay the foundation that he's not qualified to offer this testimony.
MR. DAVIS: Your Honor, I don't believe that's
11:49:07 necessary. I can go -- he's free to ask him those questions on cross-examination.
THE COURT: I'll let you proceed.
MR. DAVIS: Thank you.
MR. WISNER: With voir dire?
11:49:17 THE COURT: When we break I'll let you ask some questions.
MR. BAYMAN: Okay.
THE COURT: Outside the presence of the jury.
MR. WISNER: Yes, Your Honor.
11:49:25 MR. DAVIS: May I proceed with that question, Your Honor?
THE COURT: Yes.
Read it back, please.
(Question read.)
11:49:29 BY MR. DAVIS:

Q. Did you get that?
A. Yes.
THE COURT: You better put another question. That's not clear.
11:50:17 BY MR. DAVIS:
Q. Are -- is anxiety and depression, both individually, risk factors for suicidal thoughts or behavior?
MR. WISNER: I renew my objection, Your Honor.
THE COURT: Yes. Sustained.
11:50:26 Has he studied it, is the issue, not whether he can make a diagnosis of it.
MR. BAYMAN: Oh, I'm not asking for individual diagnosis.
THE COURT: You got to confine him to what he studied.
11:50:36 MR. DAVIS: Sure.
BY MR. DAVIS:
Q. Based upon your research and investigation, and looking at risk factors for suicidal thoughts and behavior, is depression or anxiety a risk factor for suicidal thoughts or behavior?
11:50:50 A. Yes; we established extensively on this question. So we -- we looked at 41 --
MR. WISNER: Objection; move to strike as nonresponsive at the word "yes."
MR. DAVIS: Your Honor, I believe he's allowed to
11:51:04 explain --

THE COURT: Put another question.

BY MR. DAVIS:

Q. Doctor, given the answer was "yes," why is it then important to look at placebo-controlled data or other
11:51:15 controlled data to assess whether a medication either increases the risk or separately causes suicidal thoughts or behavior?

A. Because the severity of depression is one of the greatest drivers of suicidal thoughts and behavior and completion. And if we don't control for the severity of depression, and then,
11:51:36 in essence, make it identical on average in the placebo group and in the active treatment group, then we will see imbalances in the rate of suicidal thoughts and behavior produced by the differences in the severity of depression.

In adults, severity of depression is the greatest
11:52:01 driver of suicide.

MR. WISNER: Your Honor, I move to strike this witness's answer. This is an opinion about the driver of suicidality. Again, he is not a medical doctor. He cannot be making this testimony.

11:52:11 THE COURT: No, as I understand it, he's made a study of what these things are. So, on that basis, I'll let him testify.

MR. DAVIS: Thank you, Your Honor.

BY MR. DAVIS:

11:52:18 Q. For that reason, what you just described, is that the role

and purpose of doing randomization?
A. It is certainly a good illustration of why it's so important to do randomization, so that we can balance things like the severity of depression across the treated and
11:52:35 controlled conditions of an experimental study.
We've illustrated this in the Journal of the American Medical Association in a peer-reviewed publication that I authorized.
Q. Now, the jury has heard a lot about the term "statistical
11:52:53 significance." Is that a term you familiar with?
A. Intimately.
Q. Okay. And did you and I work on a slide together to help the jury understand what statistical significance means and when results are not statistically significant?
11:53:06 A. Yes, we did.
MR. DAVIS: All right. Your Honor, permission to publish DX 7035X
MR. WISNER: Your Honor, I have one objection and it's a continuing objection to these slides, and that is, Mr. Davis
11:53:15 keeps saying that he and the expert put them together together. I think foundation needs to be laid about who did what, because I don't believe Mr. Davis is allowed to testify.
MR. DAVIS: Your Honor, I think that foundation has already been laid.
11:53:26 THE COURT: Well, you can't -- technically, the

objection is correct. It's the witness who has to put it together, not you.

MR. DAVIS: Okay. I'll just ask the question.

THE COURT: So, rely on the witness's testimony as to what was done.

11:53:41

MR. DAVIS: Sure.

MR. WISNER: No objection to that slide, though, Your Honor.

MR. DAVIS: Okay. Thank you.

11:53:45

THE COURT: Okay.

BY MR. DAVIS:

Q. Let's go to the next slide.

Dr. Gibbons, help us understand the scientific term and evaluation of statistical significance.

11:53:57

Looking at this, tell us what -- tell us what this means and whether the results are statistically significant or not.

A. So, the first thing you need to look at here is that we're talking about statistical significance now of something like an

11:54:17

odds ratio or a relative risk. You probably have heard this in the connection of this case. And what that basically means is, what is the relative risk of an event like a suicidal thought or behavior in the treated patients, patients who got Paroxetine versus the controlled patients, patients who got

11:54:38

placebo.

And the bars that you're seeing, the midpoint of that bar is what we call the point estimate of the odds ratio. It's sort of the average. It's sort of the mean. It's the relative risk. If it's a value of about 2, it means there's a doubling of the risk.

11:55:00

The length of the bar, if you focus on the one that's in the upper right corner, that's the uncertainty. That's what we call a confidence interval. Typically, it's a 95 percent confidence interval. What that means is that 95 percent of the time the true population value is going to lie within that interval.

11:55:18

Now, there's truth in the universe, and then there's a sample of data that where people who participated in a trial, and that's an estimate of that truth. So the width of that interval is telling us something about the uncertainty in our estimate around what is really true. And if we have a very small sample size in a very rare event, that the width of interval is going to be very large.

11:55:34

So with that basic introduction, the idea of statistical significance is, how likely are the data given the known hypothesis, the hypothesis we're trying to test.

11:55:53

In this case, the known hypothesis is that the odds ratio or the relative risk is 1.0. It's that middle line on this chart.

So what does that mean? What does the relevant risk

11:56:11

of 1 mean? It means that there's equal chance of observing this on drug or on placebo.

MR. WISNER: Your Honor, I'm going to object to narrative. He's actually literally asking himself questions and then answering them. I'd like it to be broken up with some questioning by the attorney.

MR. DAVIS: Your Honor, I don't beleive this is any different than what Dr. Glenmullen and Dr. Healy did.

THE COURT: You may proceed.

MR. DAVIS: Thank you.

BY THE WITNESS:

A. So in the upper right corner, the top one, we see that that 95 percent confidence interval does not include the value 1. That means it's statistically significant. It's beyond what we would expect by chance alone. And that it is in the direction of increased risk for the experimental condition versus the control condition.

The relative risk is greater than 1, the confidence interval, that band, that 95 percent confidence interval does not include the value 1, and so it's statistically significant.

The middle two bars include the value 1, and they are not statistically significant. One is moved over to the right, so our point estimate is greater than 1, but the data are still consistent with the known hypothesis. And the other is moved over to the left, so it's in the protective direction, but the

data are still consistent with the known hypothesis.

The bottom left-hand corner we see as an example of a statistically significant protective effect. Now the entire confidence interval is less than the value 1, so there is a 11:57:56 significant reduction in the risk associated with the treatment relative to the control.

BY MR. DAVIS:

Q. Thank you.

So if the horizontal bars that go across this 11:58:10 demonstrative touch or cross over the 1.0 vertical line, what does that mean?

A. So if the bars include the 1.0, it means they're not statistically significant. If they exclude it, they are statistically significant either in direction of increased harm 11:58:29 or decreased harm.

Q. What role does the statistical significance play in assessing whether or not an association exists in a study result?

A. Well, statistical significance is one of the important, 11:58:47 probably three important factors when we review a result.

So, statistical significance is important if a study has been well controlled, particularly if it's a randomized study, if we're looking at the primary end point, and we want to say something how plausible the data are given the known 11:59:06 hypothesis, which in this case is that the drug has no effect,

no increase, no benefit, no risk in terms of the outcome of interest.

So statistical significance is a key factor in determining whether or not we can conclude that there is an 11:59:22 effect that we need to explore more -- in more detail.

We also need to know, look at the point estimate, how big is the effect, what's the magnitude of the effect, and we also need to explore the confidence interval to see how precise is our estimate of that, how plausible are -- what are the 11:59:43 range of plausible values.

Q. So, do you just look at statistical significance alone?

A. No. No. We look at statistical significance, we look at the point estimate, we look at the confidence interval. And then we also look at how is the study designed. If this is a 11:59:56 study relating wearing a motorcycle helmet to -- to injury to to -- to bone breaking, then we might say, "well, this really wasn't a very good study in the first place" and statistical significance may -- you know, really doesn't matter.

Q. Now, if there's a statistical association in one study or 12:00:17 analysis, or sometimes may even -- more than one study or analysis, does that alone mean that causation has been established?

A. No. The scientific process is about drawing inferences from multiple streams of data. It's about replication. It's 12:00:35 about validation. It's about seeing the same consistent

effect. It's about looking for dis-confirming evidence. It's looking at controlled studies, randomized studies, and well controlled observational studies and synthesizing that into a coherent statement about the process that's going on in the
12:00:57 world.

MR. WISNER: Objection, Your Honor. Move to strike his testimony about what constitutes causation. Again, he's a medical expert. He's not not Bradford Hill analysis. He cannot testify about biological plausibility or the mechanics
12:01:09 of a serotonin system. He is well outside of his wheelhouse as an expert and I move to strike his answer.

MR. DAVIS: Your Honor, I believe we've already been over this.

THE COURT: The objection is sustained.

12:01:21 MR. DAVIS: Your Honor, may we have a sidebar?

THE COURT: No, let's go on. We'll take a break in a few minutes.

BY MR. DAVIS:

Q. In assessing statistical analyses, Dr. Gibbons, when you're
12:01:33 looking at whether or not there is an association or an increased risk or not, what role does consistency play?

A. Consistency is extremely important. If we have a primary endpoint and a secondary endpoint, we should be seeing a consistent pattern between them. We should be seeing, if there
12:01:53 is an effect, it should be an effect that generalizes to the

real world. It should be an effect that's seen with -- in people who have similar kinds of diagnosis. Consistency is extremely important in the scientific process.

Q. Doctor, before we look at the scientific evidence on Paroxetine and other SSRIs and the types of studies that you've described, I want to briefly discuss with you the suicide rate in the United States.

As an expert in the field of drug safety, have you studied, and are you familiar with, the suicide rate in the United States for white males of Mr. Dolin's makeup --

MR. WISNER: Objection.

BY MR. DAVIS:

Q. -- and age?

THE COURT: The objection is sustained. We're not going into suicide rates in this case. I thought I made that clear before.

MR. DAVIS: Your Honor, this is on a totally separate issue.

THE COURT: No, we're not going into that, sir.

MR. DAVIS: Okay.

BY MR. DAVIS:

Q. Dr. Gibbons, are you familiar with the frequency by which suicides in the United States are by violent means in males of Mr. Dolin's age?

MR. WISNER: Objection.

THE COURT: Sustained.

BY MR. DAVIS:

Q. Dr. Gibbons, did you prepare a slide that shows how randomization in placebo-controlled trials actually works?

12:03:17 A. Yes.

MR. DAVIS: Permission to publish DX7035F, please.

MR. WISNER: No objection, Your Honor.

THE COURT: You may proceed.

(Exhibit published to the jury.)

12:03:27 BY MR. DAVIS:

Q. All right. Dr. Gibbons, tell us -- tell us where are in terms of how randomized placebo-controlled trials work and what we're seeing up here on the screen.

A. So, what were seeing is a run-in period, which is a way of

12:03:47 detoxifying patients who might have had prior treatment, perhaps with an antidepressant, before they entered the trial.

So there's a period of washout where patients are given placebo prior to the randomization. At this point patients are then randomized into an active treatment arm or a

12:04:10 control arm.

I think we can see that in the next part of the slide.

Q. Let's go to the next slide.

Okay. What's happened there where the patients have gone from the run-in phase and they've gone into Group A and

12:04:19 Group B, what's going on there?

A. So, we've now randomized. Essentially, we've flipped a coin for each patient to decide whether or not that patient should be in the experimental arm, like a Paroxetine arm, or a control arm like placebo.

12:04:30 And the thing we notice is, initially in the population we had a fairly equal number of men and women and now we have retained that equal number, that balance of males and females in the control arm and in the -- and in the experimental arm.

12:04:47 We actually don't know, we're blinded to the status of what is Group A what is Group B. The investigators don't know that one is Paroxetine and the other is placebo. So that any expectation they may have in terms of whether or not the drug is going to work or produce a side effect is not going to bias

12:05:04 the results of the experiment.

While we see the difference between the dresses and the non-dresses as being indicative of a balance between males and females in these two arms, radiumization ensures that not only those observable characteristics but also the unobservable

12:05:26 characteristics are balanced as well.

It is only through randomization that we have that kind of complete balance between both observable characteristics and unobservable characteristics.

So at this point we have essentially equivalent

12:05:41 individuals in terms of their characteristics in these two

groups.
Q. Then what happens next. If we can go to the next slide.
Can you explain what we're now seeing on the screen, Doctor.
12:05:52 A. So, the study now is for a particular duration. And we're looking at the benefits of the treatment in terms of efficacy and we're also recording the adverse events that are encountered by patients who are participating in this trial.
Q. All right. And so can we go to the next slide.
12:06:10 What's happening here with respect to what happens to the patients who are on Paxil?
A. So, there's a group of patients who are on Paxil that will now continue on into an n unblinded, uncontrolled extension phase of this study.
12:06:26 This may be done for a variety of different reasons. It is a phase of the study that is not a part of the randomization portion of the study. In many cases, the patients and also the clinicians are now unblinded to the status that these patients actually are on Paxil. And so our
12:06:43 statistical inferences are based solely on the controlled phase of the study.
Q. For the extension phase, is there any control group that's taking the sugar pill or a placebo?
A. No. So there is no parallel control group for this phase.
12:07:00 So, imagine that there are effects that occur later in time.

The only people in this study who are measured later in time are those patients on Paxil. So the combination of those data with the controlled portion could lead to bias.

Q. And so what is the most important and critical part of a placebo-controlled randomized controlled trial?

A. The controlled phase of that trial.

Q. So that would be the phase that's in yellow that's in the middle?

A. Right. That's the phase that benefits from the randomization in the blinding of both the investigators and the patients to the actual treatment status that they received.

Q. Is it scientifically reliable to take patients who had adverse events in the extension phase and include them within the controlled phase to try to make assessments of whether there's a risk factor or an association between Paxil and placebo?

A. No.

Q. Why not?

A. Because it would bias it. We had the benefits of randomization and blindness during the control phase and now we're taking data from another period in time where patients now know what they're receiving and they have expectations about what they might be feeling based on something they've seen, or heard, or 60 Minutes article, or TV show, and that will lead to bias, and it will invalidate the entire benefit of

the randomized controlled trial.
Q. Have FDA scientists published their views about whether it's appropriate to combine or pull data from the controlled portions of the randomized controlled trial and an open label or extension-phase study?
12:08:46
A. Yes, they have.
MR. WISNER: Objection.
BY MR. DAVIS:
Q. And have you considered that information in terms of forming your opinions in this case?
12:08:51
A. Yes, I have.
MR. DAVIS: Permission to publish slide 10 and 11, Your Honor, which are DX7035H and 7035G.
MR. WISNER: I'd object to this as the best evidence rule, Your Honor. These are documents that I believe are Defendant's Exhibits and they're snapshots of them. They're going to talk about an article, put it in the guy's hands, and ask the questions.
12:09:09
THE COURT: 10 and 11?
MR. DAVIS: Yes, sir. They're part of DX1117.
12:09:24
(Brief pause)
THE COURT: Yes, I think that that slide doesn't really belong here given that there's a question about the article itself.
MR. DAVIS: Would you prefer that I call up the
12:09:53

article itself, Your Honor?

THE COURT: Well, I don't have any preference except to tell you that this won't work in the form in which you're doing it.

12:10:04 MR. DAVIS: Your Honor, I request permission to publish DX1117, which is the article from which those quotes come from. And that's in your exhibit notebook, Your Honor.

May I hand it to you?

(Document tendered to the Court.)

12:10:20 THE COURT: Is it attached to his report?

MR. DAVIS: I'm sorry?

THE COURT: Is it attached to his report?

MR. DAVIS: That article is not attached to his report.

12:10:50 THE COURT: Do you have a copy?

MR. WISNER: I do. No objection.

MR. DAVIS: Thank you.

Let's call up DX1117. And can we call up the title and the author at the title, Mr. Holtzen.

12:10:57 (Brief pause).

BY MR. DAVIS:

Q. Dr. Gibbons, what's happened the name of this article and who are the authors?

A. Suicide Rates in Short Term Randomized Controlled Trials of

12:11:09 Newer Antidepressants. Tarek Hammad, Thomas Laughren and

Judith Racoosin.
Q. Do you know Dr. Hammad and Dr. Laughren?
A. I do.
Q. What role do they play at the FDA?
12:11:26 A. Tom was the former head of the psychopharmacology division at the FDA. He was the head of it at the time this article was published. And Dr. Hammad was one of the analysts and members of that psychopharm division.
Q. Was Dr. Laughren one of the FDA scientists who was involved
12:11:52 with the 2006 FDA adult analyses on suicidality?
A. Yes, he was.
Q. Now, with respect to this particular publication, let's go to --
(Brief pause).
12:12:05 BY MR. DAVIS:
Q. And in this publication by FDA scientists, what is discussed about whether or not it's appropriate to pull data from randomized controlled portions of a trial and open label extension phases?
12:12:25 A. There reiterating the point that we just made with the previous slide, that those data from the open label portions of a randomized controlled trial or open label studies, in and of themselves--and by "open label" I mean a study that doesn't have the benefit of randomization and a study where the
12:12:44 patients actually know what there receiving in terms of

treatment, there isn't a placebo arm, there isn't a comparable arm to compare the active treatment to--should not be pooled or included in these kinds of -- of metaanalyses of randomized controlled trials.

12:13:04 Q. Do you grow with these FDA scientists that say when you that and you pull those two different types of studies together that they are subject to bias and could lead to misleading results?

A. Yes, I agree with that completely.

12:13:17 Q. All right. Now, if an expert such as Dr. Healy or Dr. Ross testified in this case that the analysis that they relied upon or utilized actually combined placebo-controlled data with open label extension phases or even active controlled data, is that scientifically reasonable and appropriate to do for purposes of

12:13:38 assessing risk factors for Paxil and whether or not it increases the risk of suicidal thoughts or behavior?

A. No.

MR. WISNER: Objection; improper opinion. This witness cannot criticize medical doctors and

12:13:49 psychopharmacologists who have Ph.D.'s in how these drugs are made and used in real life. This is way beyond his wheelhouse again.

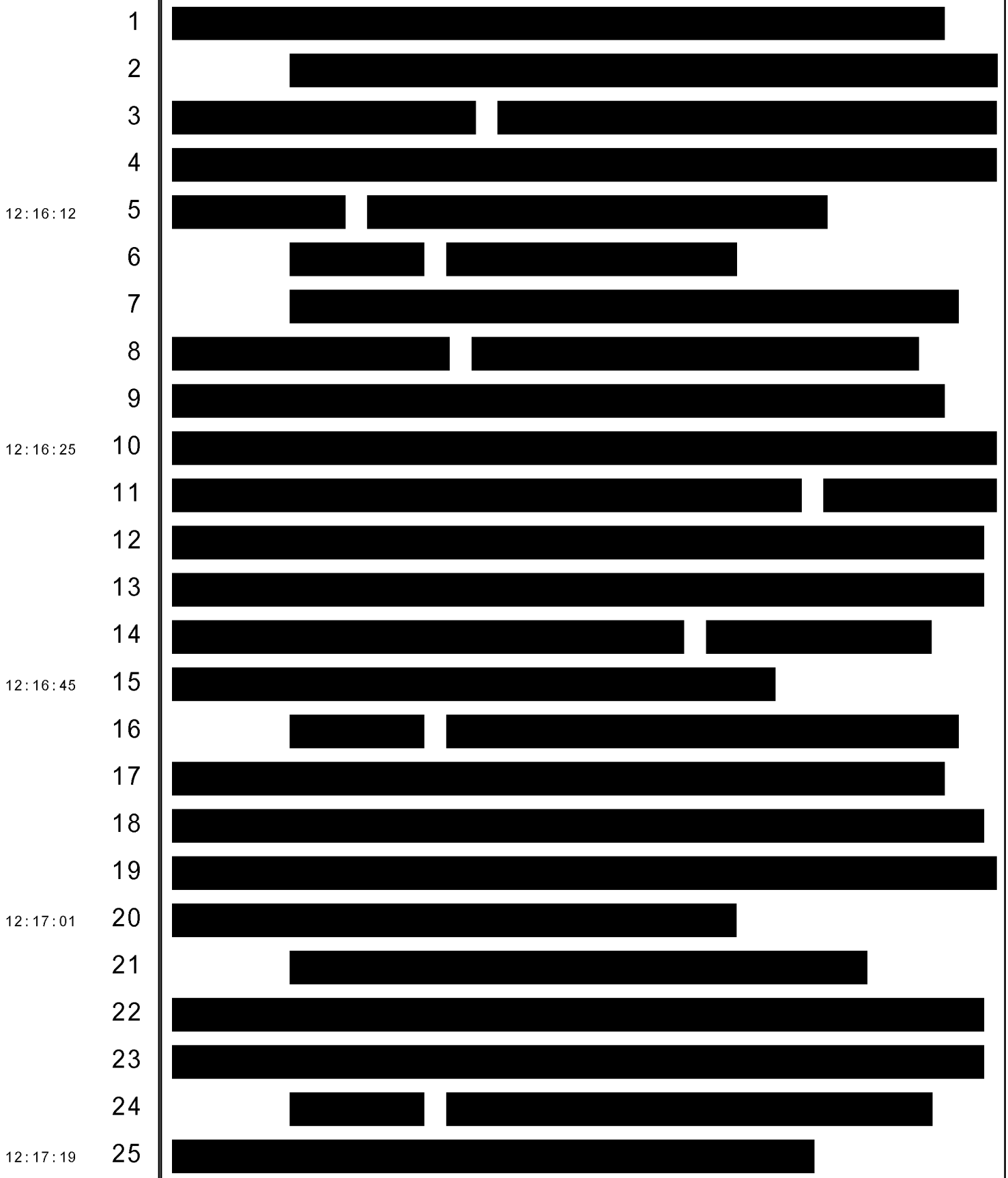
MR. DAVIS: Your Honor, the testimony --

THE COURT: Let's take the noon recess and see if we

12:14:01 can work on this issue.

(The following proceedings were had out of the presence of the jury in open court:)

[redacted]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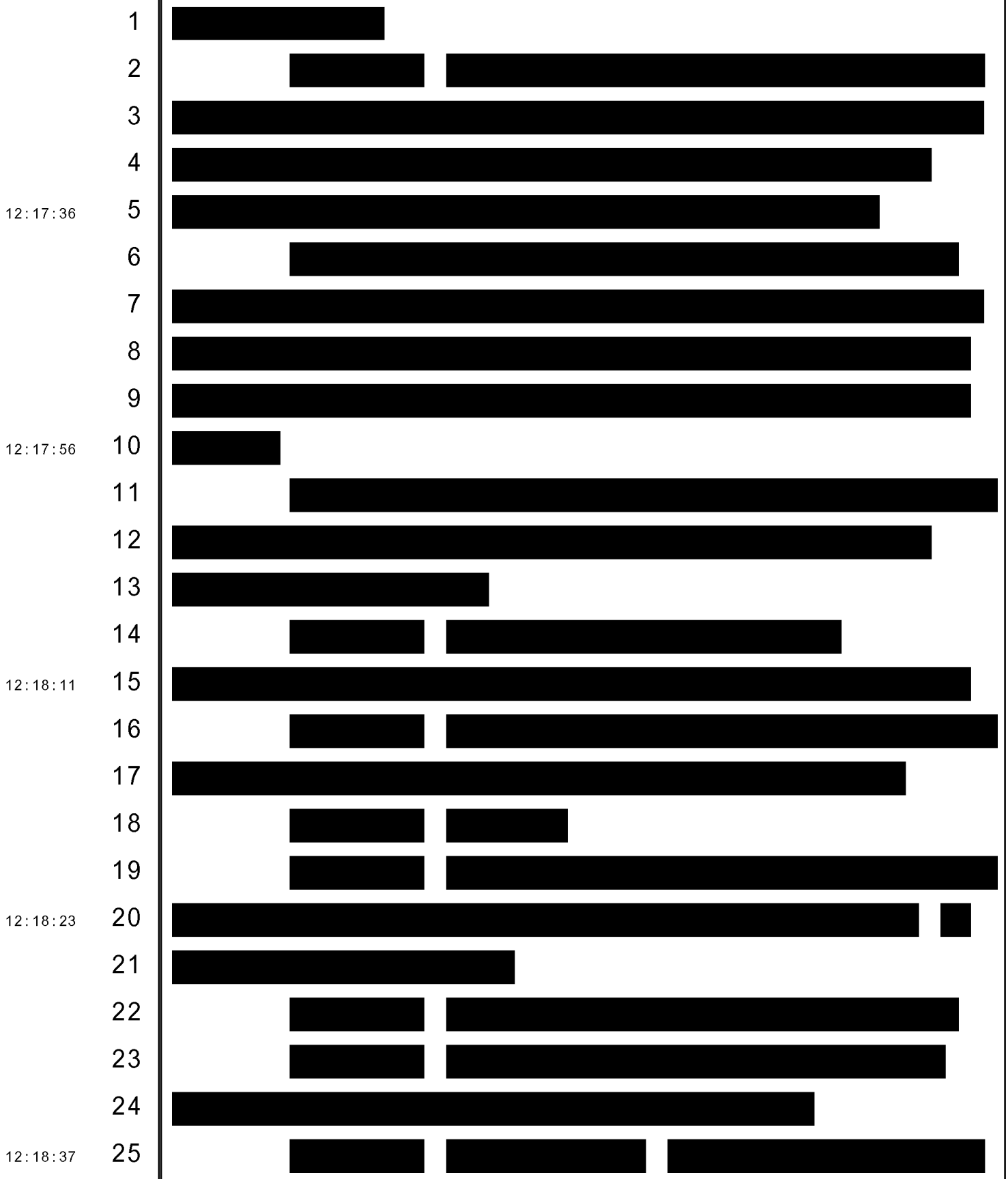
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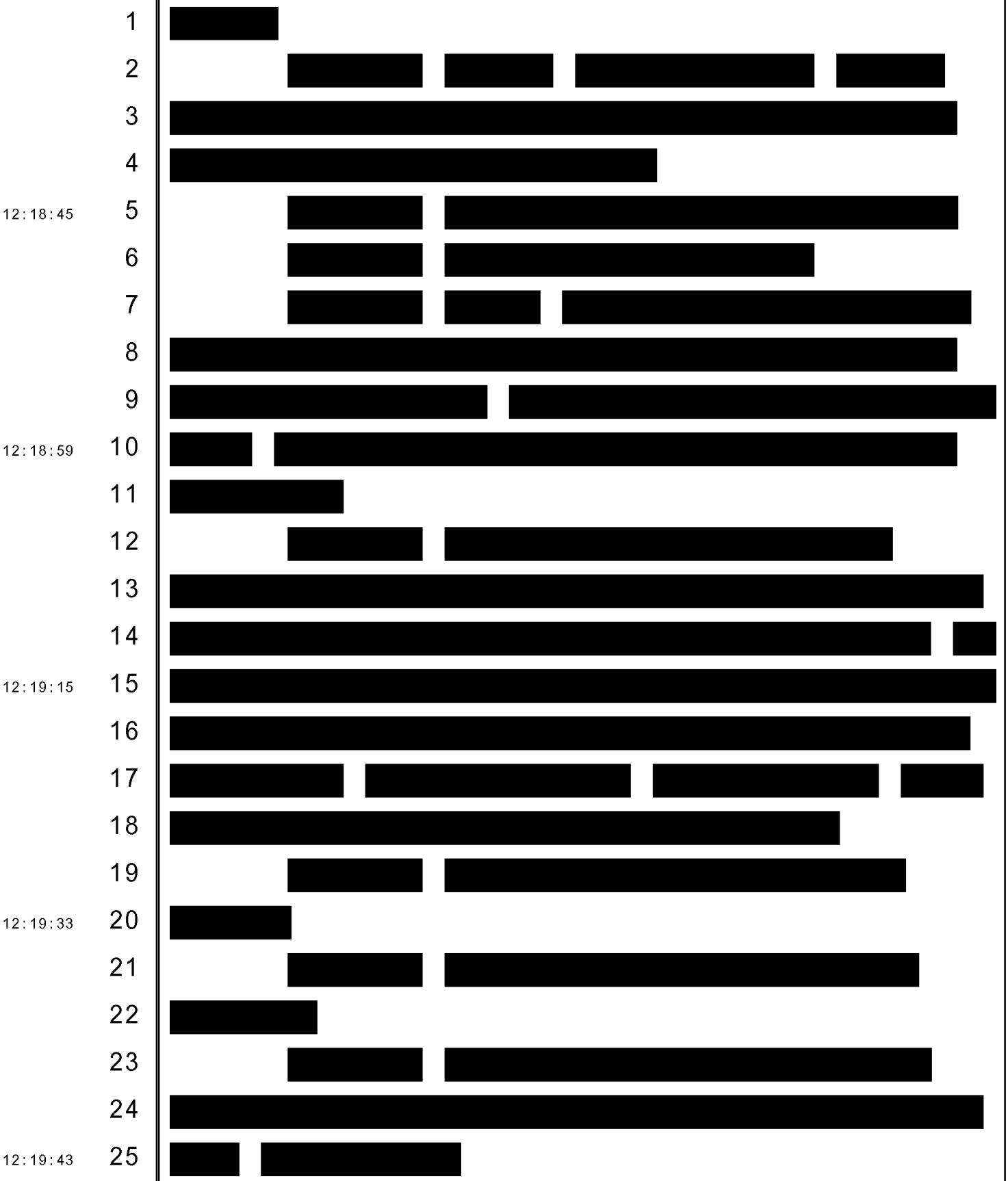
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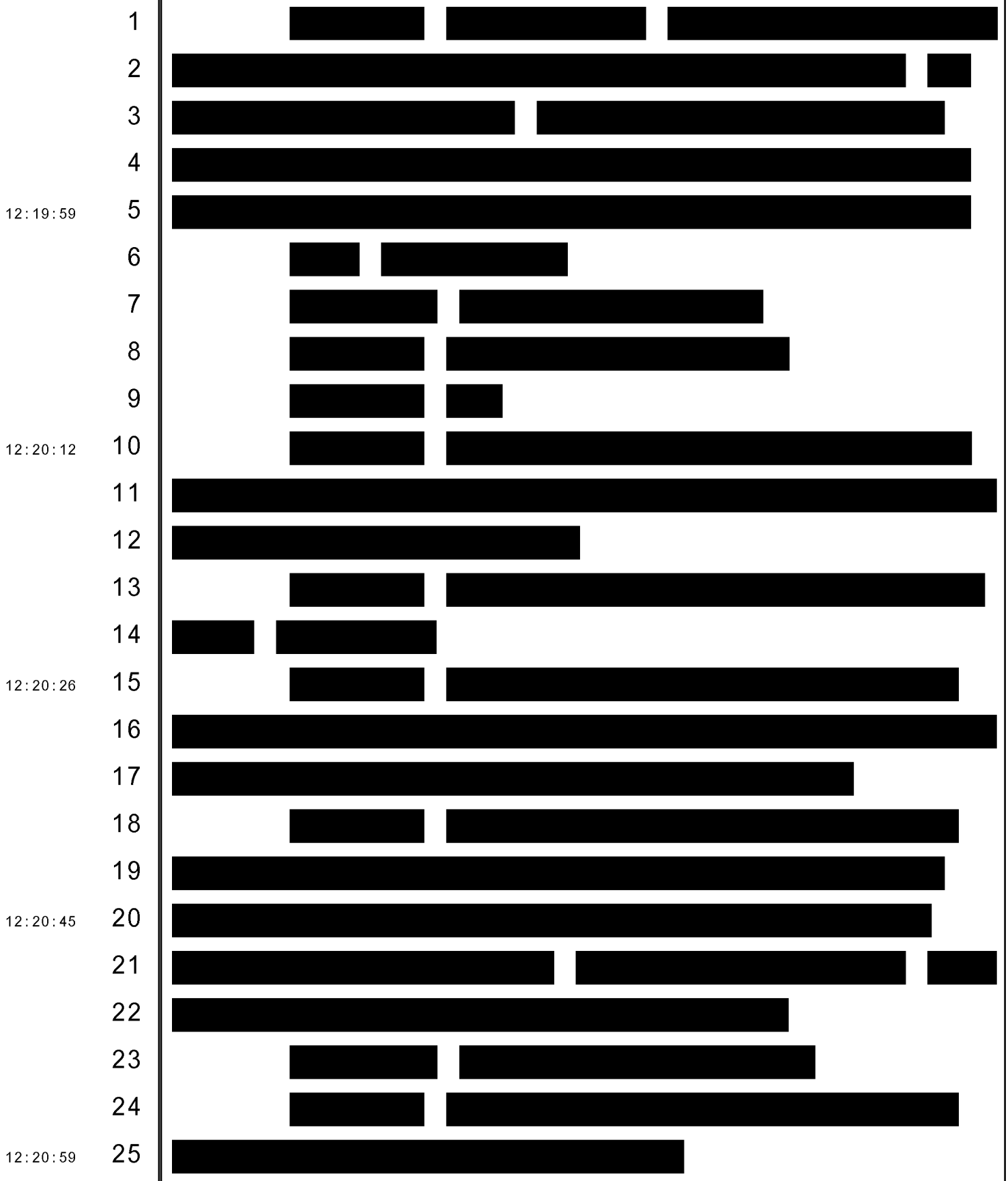
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(Luncheon recess taken from 12:30 o'clock p.m. to 1:30 o'clock p.m.)

* * * * * * * *

I CERTIFY THAT THE FOREGOING IS A CORRECT TRANSCRIPT FROM THE RECORD OF PROCEEDINGS IN THE ABOVE-ENTITLED MATTER

/s/Blanca I. Lara April 4, 2017